NABH

NATIONAL ACCREDITATION BOARD FOR HOSPITALS AND HEALTHCARE PROVIDERS

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ACCREDITATION STANDARDS FOR ETHICS COMMITTEE

KEEPING RESEARCH PARTICIPANTS SAFE & PROTECTED

AUTONOMY | BENEFICENCE | NONMALEFICENCE | JUSTICE

FOREWORD

Ethics Committee is an integral and critical part of Clinical Research, since most of the trial procedures are reviewed, checked and monitored by them. The aim of ethics committee accreditation is to provide proper system and procedures with quality review structure, in order to establish confidence in India's research methodologies and capabilities.

This accreditation is meant for evaluating the performance and capacity of the ethics committee. The main objective of ethics committee accreditation is to bring trial procedures and policies at par with global standard to ensure overall protection of trial participants which increases the safety and therefore reduces legal risks. In order to strengthen the clinical evaluation of new drugs, clinical trials should be conducted ethically with oversight of accredited ethics committee.

Standards are pre-requisite for the promotion of safe, effective, competent and ethical procedure of clinical trials. They help clinical research professionals to evaluate the services being provided by them and also act as a catalyst for self-regulation and improvement.

The clinical trial professional are the frontline staff with whom the subjects, their families and visitors interact first hand. Their knowledge, experience, clinical judgement, skills, attitude, communication and other soft skills thus make all the difference in the ultimate delivery of quality care to the subjects.

Ethics committee standards have been framed with a view to ensure principles of good governance and ethical standard for evaluating the quality of services being provided by the clinical trial site including investigator as well as the site staff there by providing a basic platform for continual improvement.

These standards are applicable to all the hospital/institution where clinical trial procedures are being conducted irrespective of their size, role and complexity. It will serve as guidelines to ethics committee for facilitating safe, competent and ethical trial practices within their hospital/institution or named unit.

Apart from serving as a framework for evaluation of the quality of clinical trial services rendered, these standards will also provide guidelines to assist clinical research professionals in decision making and will support their efforts by outlining the professional expectations from the clinical trial services. The standards are on the same framework as has been for the NABH standards for Health care organizations.

Ethics committee standards focus on various professional, administrative and governance aspects of clinical trial. It consist of 10 Standards and 49 objective elements.

Objective elements are required to be compiled with, in order to meet the requirement of a particular standard. Similarly, standards are required to be compiled with, in order to meet the requirement of an ethics committee accreditation.

The draft standards on Clinical trial Sites and investigators are ready for operationalization provided Industry finds them useful & valuable for participants safety, a copy of the draft standards is attached herewith.

This Standards is helpful in following ways:

1) To the ethics committee to assure trial participants that they are receiving high quality care.
2) To the clinical research staff/professionals to know exactly what is essential to provide quality and that measures are in place to determine whether the care meets the standards.
3) To the NABH Assessors for conducting assessments
4) To CROs/Sponsors in reducing the risk involved in clinical trials by third party certification.

Standards for all the three components (Ethics Committees, Clinical Trial sites & Investigators) would be under constant review process. Comments and suggestions for improvement are appreciated. We seek your valuable input & support to our endeavor in this regard.

Dr. Atul Mohan Kochhar

(CEO-NABH)

ACCREDITATION OF ETHICS COMMITTEE

OBJECTIVES

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.

OUTCOMES

- 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.

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.
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/ terms of reference 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 reviews.
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 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.

Interpretation:

1. For Institutional Ethics Committee:

a. The ethics committee should have a documented policy to establish under whose authority it is governed. Administratively governs means that Institution supports, may establish or oversee the establishment of the ethics committee and provides support to the ethics committee activities including training, resources and infrastructure.

b. Name of the ethics committee should have reference to the institution under whose authority it is established and it should be reflected in all documentations and communication. [Institution can be a Hospital, CRO]

2. For Independent Ethics Committee:

a. In case the hospital uses the services of an independent ethics committee it should be in consonance with the new Drugs & Clinical Trial Rules 2019 which states that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 km of the clinical trial site

b. There should be an MOU between the independent Ethics Committee and the Institution addressing all the administrative and functional aspects as per New Drug & CT Rules 2019 and NABH standards.

Documentary Evidences:

a. Letter of Authority on Institutional Letter head for Institutional Ethics Committees

b. Notarised MOU for Independent Ethics Committees

c. Policy statement of the institution/Independent Ethics Committee should reflect the establishment and administrative governance of the committee highlighting the autonomy in its functioning and decision making.

d. Records and documents have the name of the ethics committee.

Outcome Ethics committee is a part of the institution which governs it.

Onsite assessment: 1. Review of documents at the site 2] Policy statement, documents reflecting the association of the ethics committee to the Institution. 3] Interview

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

Interpretation:

a. A policy statement is issued authorising the ethics committee of its independence in functioning [decision making] by the institution head.

b. The ethics committee shall not have any institutional official with any conflict of interest as a member. [For Ex-Director, CEO, and other members of management including board members]

Documentary Evidence:

a. Policy/MOU (as applicable) stating that ethics committee is independent in its functioning and decision making issued by the institution.

b. Ethics committee roster (membership list) and sample review of minutes of meeting must demonstrate this requirement.

Outcome: There is no undue influence by the institution on the decisions made by the ethics committee.

Onsite assessment: 1. Review of documents at the site 2] Interview

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

Interpretation:

a. The ethics committee shall adhere to existing applicable rules and regulations for its formation and functioning which includes the registration of the ethics committee, criteria for selection, appointment, tenure, resignation, schedule of meeting, reporting to regulatory authority and other administrative process. We at present follow New Drugs & Clinical Trial Rules 2019 and ICMR 2017 guidelines.

Documentary Evidence:

a. Terms of reference (TOR) for the ethics committee. [Composition, Criteria for member selection, Procedures for new induction & resignation of members, Roles and responsibilities of members, Scopes and tenures of committee members, Frequency and quorum for meeting and training for members]

b. Ethics committee roster (membership list).

Outcome: Ethics committee formation and functioning meets the regulatory requirements.

Onsite assessment: 1. Review of documents at the site 2] Ethics committee SOPs, TOR, Communication of appointment and resignation 3] Interview

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.

Interpretation:

a. There should be an SOP on SOP to specify the time frame and other conditions for control and amendments to the SOP.

b. Develop SOP on SOP detailing the control, revision, amendment, retention and destruction of EC documents.

Documentary Evidences:

a. There are procedures for preparing, updating and amending and distribution of the SOP.

Outcome There is clarity and uniformity in the ethics committee procedures.

Onsite assessment: 1] Review of documents at the site including SOP 2] SOP on SOP 3] Interview

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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, affiliations, gender, age), 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.

Interpretation:

a. There should be documented SOPs for these mandatory procedures. There may be separate or single SOP(s) to include all these procedures.

b. SOPs should have a scope, detailed process and applicable templates/ checklists/flow charts and be as per applicable rules and regulation.

c. SOP should have authorised signature of individuals who has prepared, reviewed and approved the SOP. SOPs should include issue date, revision date and validity date.

d. SOPs should be accessible to all stake holders for reference.

Documentary Evidence:

a. Required SOPs are in place and made available to all stakeholders.

Outcome: The ethics committee functioning is standardised and as per applicable rules and regulations.

Onsite assessment: 1] Review of SOPs at the site for the mandatory requirement 2] Interview

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.

Interpretation:

a. The ethics committee has procedures to decide the adequacy of membership required in terms of number which should not be less than 7 and shall include 5 special areas as per applicable rules and regulations. Inst. EC should have at least 50 % members from outside the Institution. EC should have along with chairperson and member secretary, clinicians, basic medical scientists (preferably one pharmacologist), legal experts, social scientist/representative of non-governmental voluntary agency/ philosopher/ethicist/theologian or a similar person.

b. Composition is multidisciplinary and multisectorial, with appropriate age and gender representation and is adequate for its functioning.

c. The chairman should be from outside the institution, one member will be designated as member secretary who will run the ethics committee business, and record minutes. Either the chairman or his designee will be the signatory to the documents. SOP for member selection and number of members required is based on number and type of protocols reviewed.

Documentary Evidences:

a. Ethics committee roster/ membership list: includes details on the age, gender, qualification, area of expertise, organisation details, role in the ethics committee, address and contact details, present and past affiliation to the institution. Chairman should be from outside the institution. Members also include following representatives: basic medical scientists (preferably one pharmacologist), legal experts, a lay person, social scientist/representative of non-governmental voluntary agency/ philosopher/ethicist/theologian or a similar person and clinicians.

b. CV of ethics committee members.

c. Confirm if SOP covers this requirement.

Outcome The composition meets the regulatory requirement and responsibilities of ethics committee members are well defined.

Onsite assessment: 1] Review of relevant SOP 2] EC roster/membership list, 3] Samples review of EC meeting minutes 4] Interview

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

Interpretation:

a. Procedures are in place for calling subject experts [in case the ethics committee does not have one as its member and representatives of vulnerable subjects] and they will be non-voting members. The

subject expert should be preferably from outside the institution. This is to ensure that the scientific review is appropriate, approval of the trial meets the regulatory requirements and vulnerable population is protected from undue risk.

b. Example for subject expert: if there is no paediatrician on board and the proposal involves children then a paediatrician should be invited for review of the proposal.

c. Representative for the vulnerable group is an individual who understands the issues of that population and has been working with this group. The representatives can be non-medical personnel. Example: in case of an HIV trial a social worker who has experience in working with HIV patients may be invited.

Documentary Evidence:

a. Name and qualifications of the experts and representatives should be documented. Their attendance and viewpoints should be reflected in the meeting minutes.

b. Documented evidence of invitation to the meeting, curriculum vitae of experts and the representatives.

c. Confirm if SOP covers this requirement.

Outcome: 1] Scientific assessment and scientific validity of protocol is ensured. 2]Protection of vulnerable subject is ensured.

Onsite assessment: 1] Review of documents at the site 2] Interview

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

Interpretation:

a. There should be a documented term of reference/SOP for appointment, reconstitution, and resignation of member as per applicable rules and regulations. Example: The Ethics committee may be reconstituted after every 5 years or earlier as defined in the SOPs.

b. There must be reconstitution of at least 50% of the members who have completed 3-5 years in the Ethics Committee. Over a period of 6-10 years 100% of the members should be changed. No member shall continue beyond 2 tenures in the same Ethics Committee.

Documentary Evidence:

a. Confirm if SOP covers this requirement.

b. All appointments, reconstitutions, resignations are documented, dated and filed.

c. Ethics committee roster/ membership list.

d. Ethics Committee meeting minutes or evidence of some communications.

Outcome: At all times composition of the ethics committee is adequate and appropriate for it's functioning.

Onsite assessment: 1] Review of documents at the site 2] Interview

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1.3.4 Roles and responsibilities of members shall be well defined.

Interpretation:

a. The Ethics committee assigns responsibilities to the members with the objective to involve every member in decision making process. Example: a) The member secretary can be delegated

administrative activities, meeting minute's finalization, circulation and checking the qualification & expertise of the Principal Investigator (P.I) for the proposed project b) There may be primary reviewers for the protocol, serious adverse events etc. c) The Legal person of the Ethics committee may be the primary reviewer of the contract d) Lay person: may be the primary reviewer for the informed consent document language – whether it would be understandable to the subjects. There should be every attempt to ensure meaningful participation of layperson, theologian/social scientist and legal persona for protecting subject's right, safety and wellbeing and this should be demonstrated. One person may be delegated to update the members of all new regulatory notifications and organise trainings.

Documentary Evidence:

a. Confirm if SOP /Policy document covers this requirement.

b. Minute of meeting (MOM) to demonstrate the participation of all members.

Outcome: Every Ethics committee member contributes to the decision making with a meaningful participation.

Onsite assessment: 1] Review of documents at the site 2] Interview

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

Interpretation:

a. The Ethics Committee procedures should demonstrate schedules for orientation courses in bioethics, applicable rules and regulations (New Drug & CT Rules 2019 and ICMR 2017 guidelines), local social and cultural norms and relevant SOPs. Members are trained on assessing the risk benefit, evaluating the scientific validity and assessing the ethical issues. Subject experts in bioethics may be called for training in ethical issues.

b. GCP training can be conducted by one who is a recognized GCP trainer. All Ethics committee members should undergo a refresher course in GCP annually.

c. Only GCP trained individual can be inducted into the EC

Documentary Evidence:

a. Training schedule

b. Documentation of all training/ Records of training materials/ Tools used, CV of the trainer,

c. Documentation of Evaluation of training. (Pre and Post test results, Follow up action taken as relevant and effectiveness as member of the EC after training)

d. Confirm if SOP covers this requirement.

Outcome: Ethics committee members are competent to make decisions to protect the trial subject.

Onsite assessment: 1] Review of documents at the site 2] Interview

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1.3.6 Conflict of interest and confidentiality shall be addressed at the time of composition and at the time of every meeting. Any conflict of interest and confidentiality is declared on appointment, and before every meeting.

Interpretation:

a. The Ethics Committee members should declare conflict of interest. Examples are as follows:

i. If Ethics Committee member is also the investigator then he/she will declare the conflict of interest to the chairman and will exempt himself/herself from the review process and voting. The chairman will reassess the quorum when any member withdraws from the decision making and this shall be recorded in the minutes.

ii. Non-Financial COI includes any family members like spouse, children etc.

b. The Ethics Committee members should be aware of the conflict of interest policy.

c. Investigator shall declare any conflict of interest while submitting the documents for review. He also submits the budget of the trial to the ethics committee for financial transparency.

Documentary Evidence:

a. Conflict of Interest disclosure template/form.

b. Check list of what constitutes conflict of interest (financial and/non-financial)

c. Ethics Committee minutes of meeting.

d. Records of relevant communications.

e. Confirm if SOP covers this requirement.

Outcome: Decision making is independent of any personal conflict of interest, financial or non-financial.

Onsite assessment: 1] Review of all relevant documents and records at the site 2] Interview

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.

Interpretation:

a. Rights and responsibilities of the subject as per the rules and regulations will be documented. EC should interview some subjects periodically to ascertain whether they have been informed about their rights and responsibilities and document the same.

Documentary Evidences:

a. Document listing all the rights and responsibilities in a charter.

b. Confirm if SOP covers this requirement.

C. Documentary evidence of EC interview of subjects about their rights and responsibilities.

Outcome The ethics committee members understand rights and responsibilities of the trial subjects.

Onsite assessment: Review of documents at the site 2] Interview

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

Interpretation:

a. Informed consent documents should include the mandatory language as per the regulations. This includes the statement that the participation in the trial and withdrawal is voluntary. The withdrawal should be with prior intimation.

b. The ethics committee has the authority to a) verify with the subject, b) witness a consenting process c) review the consent process in the written record and the audio video consent DVD for vulnerable subjects only as per the latest gazette notification.

Documentary Evidence:

a. Informed consent documents should include the mandatory language as per the regulations. This includes the statement that the participation in the trial and withdrawal is voluntary. The withdrawal should be with prior intimation.

b. Assessors will review corresponding source documents for subjects who have withdrawn from the study (if applicable).

c. Confirm if SOP covers this requirement.

d. Ethics Committee minutes of meeting.

Outcome: The ethics committee ensure the subject/ LAR participates and withdraws in the trial without any coercion or influence.

Onsite assessment: 1] Review of documents at the site 2] Interview

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

Interpretation:

a. The Ethics Committee should have a process to ensure that subjects are well informed of all the risks and benefits in the clinical trial initially and on an on-going basis throughout the trial period. [Ex-if there is a major amendment of Suspected Unexpected Serious Adverse Reactions (SUSAR) from other sites then subject must be informed and re-consenting to be done]

b. Informed consent document should include the risks and benefits of the trial in a language that the subject can easily understand. Example: a] Ethics Committee should request informed consent document in all applicable local languages for subjects. Ethics Committee verifies translations/back translations of the informed consent document for appropriateness of language and scientific content.

Documentary Evidence:

a. Informed consent documents should include the mandatory language as per the regulations.

b. New safety information should be promptly communicated to subjects and should be documented in the source notes and re-consenting should be done in a timely manner.

c. Minutes of meeting.

d. Confirm if SOP covers this requirement.

Outcome: Ethics committee ensures that subject has information of risks and benefits while participating in the trial.

Onsite assessment: 1] Review of documents at the site 2] Interview

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1.4.4 Confidentiality and privacy of subjects shall be protected.

Interpretation:

a. The ethics committee should have a process to address the breach of confidentiality and privacy. Example a] shall not reveal the subjects details publicly. b] Safe Storage space of all the documents is available and access is restricted to ensure confidentiality of trial records.

b. Information should be provided in the informed consent document on the confidentiality and privacy of subjects.

Documentary Evidence:

a. Unique coding of the study subject files is done (example. assigning subject ID for the clinical trial).

b. Confirm if SOP covers this requirement.

Outcome: Confidentiality and privacy of subject is safe guarded. Ethics committee protects subject's right.

Onsite assessment: 1] Review of documents at the site 2] Interview

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

Interpretation:

a. Equitable refers to a state of being fair so that the benefits and burdens of research are fairly distributed (emphasize on equal distribution). There should be evidence of unbiased selection of subjects reflected in the periodic review and should be as per the inclusion and exclusion criteria of protocol. [There can be a monitoring schedule and this should be done by the EC members]

Documentary Evidence:

a. Subject log demonstrates a varied area of subject selection [references, other hospital patients, from data base]
b. There is a process whereby the ethics committee periodically reviews subject's selection details.
c. Confirm if SOP covers this requirement.

Outcome: The selection ensures equal distribution of benefits and risks of trial.

Onsite assessment: 1] Review of documents at the site 2] Interview

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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.

Interpretation:

a. The ethics committee should have and follow a mechanism to ensure that compensation is paid to the subject as per informed consent document, contract and applicable rules and regulations. Here compensation means payment done for participating in the trial. Which will include travel expense. The site can prepare invoices and take signatures from patients for amount received.
b. The amount paid should be approved [to be verified only] by the ethics committee.

Documentary Evidence:

a. Visit schedule of subjects as per protocol
b. Subject files including informed consent document
c. Records of payment
d. The trial contracts
e. Confirm if SOP /Policy document covers this requirement.

Outcome: Patients service and inconvenience is compensated.

Onsite assessment: 1] Review of documents at the site 2] Interview

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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.

Interpretation:

a. Ethics committee ensures that required medical care is provided for serious adverse events as per applicable rules and regulations. All costs related to the hospitalization and treatment of the subjects will be borne by the Sponsor. **[Refer to New Drug & Clinical Trial Rules 2019]**

b. SAE reporting timelines and medical care provided is as per applicable rules and regulations.

c. Ethics committee is aware of the applicable rules and regulations and ensure that investigator is also aware and follows the requirement.

Documentary Evidence:

a. Serious adverse event reports, source documentation, hospital records.

b. Communications about the SAE from/to the Investigator, Ethics Committee, Regulatory Authority and Sponsor.

c. Meeting minutes

d. Reporting timelines as per rules and regulations following the death of the subject.

e. Confirm if SOP /Policy document covers this requirement.

Outcome: Subject rights protected as per rules and regulations.

Onsite assessment: 1] Review of documents at the site 2] Interview

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

Interpretation:

a. The ethics committee should have and follow a mechanism to ensure that compensation is paid to the subject as per applicable rules and regulations

b. The ethics committee should have and follow a mechanism to track for injury to the subject due to noncompliance of protocol.

Documentary Evidence:

a. Serious adverse event reports, source documentation, hospital records.

b. Communications about the SAE from/to the Investigator, Ethics Committee, Regulatory Authority, Sponsor.

c. Minutes of Meeting

d. Root-cause analysis of SAE

e. Documentary evidence of communication with investigator and proof of compensation received

f. Confirm if SOP covers this requirement.

Outcome: Ethics committee is responsible for the welfare of the subject.

Onsite assessment: 1] Review of documents at the site 2] Interview

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

Interpretation:

a. The Ethics Committee should have a subject grievance redressal process. Ethics Committee may contact subjects randomly, interview subjects during visits.

b. The informed consent document should contain contact number(s) of the designated member(s) of the Ethics Committee.

Documentary Evidence:

a. Process for grievance redressal. Confirm if SOP /Policy document covers this requirement.

Outcome: patient's rights are respected.

Onsite assessment: 1] Review of documents at the site 2] Interview

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.

Interpretation:

a. The ethics committee has a dedicated secretariat for support and for the smooth running of the ethics committee. There should be a clear terms of reference and budget for resource allocation by the institution.

b. Individual must be designated for the administrative activities and record keeping for the Ethics Committee.

Documentary Evidences:

a. Separate human resource and budget allocation for ethics committee functioning.

b. Details of ethics committee compensation for their services.

c. Roles and responsibilities of the ethics committee secretariat.

d. Confirm if SOP covers this requirement.

Outcome: The ethics committee is able to function regularly and meets the mandatory timelines as required.

Onsite assessment: 1] Review of documents and records at the site 2] Interview

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1.5.2 There shall be financial transparency of Ethics Committee activities and functioning.

Interpretation:

a. The ethics committee maintains financial records which include: a) details of ethics committee fees for their services b) Honorarium payment to each of the members and c) Other expenses incurred.

Documentary Evidences:

a. Financial records including annual financial audit reports

b. Confirm if SOP covers this requirement.

Outcome: Ensures financial transparency and addresses ethical conduct and conflict of interest.

Onsite assessment: 1] Review of documents and records at the site 2] Interview

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1.5.3 There shall be a procedure for communication between ethics committee, investigator/ relevant site staff, institution and regulatory authority.

Interpretation:

a. Ethics committee has a process for communication with the Principal Investigator and the Institution,

and the regulatory authority. This is important for resolving issues or bringing to notice any noncompliance. Any change in the Principal Investigator should be approved by the Ethics Committee and Notified to the DCGI.

b. The communication may be through written communication or email. Communications also should be of all recent notifications and recent changes in Clinical Trial Regulation.

Documentary Evidences:

a. Records of written communication/correspondence.

b. Confirm if SOP covers this requirement.

Outcome: Assures coordination between all research stake holders and with the regulatory authority.

Onsite assessment: 1] Review of documents and records at the site 2] Interview

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.

Interpretation:

a. The ethics committee should review every clinical trial proposal initial, amended or periodic as per applicable rules and regulations. This also includes the CV of Principal Investigator (P.I), Co-Investigator to and other team to ensure the qualification and expertise is appropriate for the proposal, the investigators undertaking, and advertisements.

b. The ethical review should be done through formal meetings and not through circulations of proposals.

c. For the initial review, the investigator submits all essential documents for review prior to the ethics committee meeting so that the ethics committee has sufficient time to review the documents (at least 10 days prior to the meeting). It is preferable that the investigator presents the protocol and offer clarification during the ethics committee meeting.

d. For periodic review, the investigator submits the relevant details like – number of subjects recruited, serious adverse events, protocol deviations, non-compliance and summary of amendments.

e. Exempt and expedited review is as per EC SOP and guided by rules and regulation.

Note: a) Initial review is the first review of the proposal. b) Amendments are any changes/updates to the approved protocol. c) Periodic review is review of the trial status and analysis of risk to subjects in an ongoing trial previously approved by the ethics committee. Periodic can be once in three months or six months depending on the risk status of the trial or if it involves vulnerable population. Principal Investigator (P.I) is made aware of the periodicity to submit the documents for review. d) Expedited review can be done if there is any minor changes in the trial related documents. e) Exempt from full board review is accepted in cases of registry studies.

Documentary Evidences:

a. Confirm if SOP /Policy document covers this requirement.

b. Minutes of meeting

c. Applications and submissions to the ethics committee.

d. Communication with the PI and records of circulation of documents to ethics committee.

Outcome: There is sufficient time for proper assessment of the study related document prior to approval. The ethics committee frequently evaluates the risk and benefit status of the trial.

Onsite assessment: 1] Review of documents and records at the site 2] Minutes of meeting 3] Interview

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.

Interpretation:

a. Ethics committee should ensure that scientific evaluation and ethical review of the trial is done prior to

approval to ensure that subjects are exposed to minimal risk. The ethics committee should assess the risk-benefit ratio for every proposal. Ethics committee assess whether the study would benefit the population especially in placebo-controlled trials. Scientific committee may support the ethics committee. Appropriate experts should assess the proposal as required. Example: A proposal of paediatric population should be assessed by a paediatrician.

Documentary Evidences:

a. Confirm if SOP covers this requirement.
b. Benefit risk assessment template, checklist to assess risk, records of assessment (whichever is used by the ethics committee).
c. Informed consent document is reviewed for ethical review.
d. Minutes of meetings.

Outcome: Ethics committee understands minimal risk and assures safety of subjects.

Onsite assessment: 1] Review of documents at the site 2] Interview

---

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

Interpretation:

a. The informed consent document should have all the essential elements as per applicable rules and regulations.
b. Assent form is applicable in paediatric trials where the child is capable of making decisions and voluntarily confirms his or her willingness to participate in the clinical trial after being informed of all aspects of the trial that is relevant to his or her decision making.

Documentary Evidences:

a. Checklist of the essential elements of informed consent document.
b. Certificate of translation and back translations from different individuals.
c. Confirm if SOP covers this requirement.
d. Minutes of meeting

Outcome: Patients right and welfare is ensured.

Onsite assessment: 1] Review of documents at the site 2] Interview

---

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/Legally authorized representative (LAR)/Impartial witness are provided appropriate information, adequate time is given and impartial witness used as applicable.

Interpretation:

a. The process should ensure that adequate time is given to the Subject/ legally authorized representative (LAR) for comprehension of information.

Examples: a) There should be evidence that queries and concerns of subject are addressed. b) There

should be a provision for subjects to take opinion from family physician if they want. c) Audio video recording should be carried out as per applicable rules and regulations and sponsors requirement. d) The subject should be provided with an informed consent document in the language he/she knows and understands. e) Subjects should sign first in front of the investigator/delegate and thereafter the investigator/delegate should sign. f) A copy of the signed informed consent document should be provided to the subject.

Documentary Evidences:

a. Checklist/Flowchart for reviewing the consenting process
b. Informed consent document in the local languages are submitted and approved.
c. Confirm if SOP covers this requirement.

Outcome: Subjects/Legally authorized representative (LAR) sign the informed consent form after complete understanding of all information in the informed consent document

Onsite assessment: 1] Review of documents at the site 2] Interview

---

1.6.5 Recruitment strategies shall be evaluated.

Interpretation:

a. The ethics committee should ensure that the advertisements do not induce the participants. The language and content of the informed consent document is verified.
b. Recruitment strategies are reviewed by the ethics committee. During the presentation of the study protocol by PI, one of the slides should indicate the details of the recruitment strategies.
c. The ethics committee ensures that the organization / Principal Investigator shall have a recruitment policy to ensure unbiased selection of adequate number of suitable subjects according to the protocol.

Documentary Evidences:

a. Recruitment strategy
b. Advertisement materials
c. Meeting Minutes
d. Confirm if SOP covers this requirement.

Outcome: Selection of subject is fair and equitable without coercion.

Onsite assessment: 1] Review of documents at the site 2] Interview

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

Interpretation:

a. Special group includes pregnant/nursing women, children, geriatric (elderly) etc. Vulnerable group includes socially and economically backward/disadvantaged subjects, mentally challenged subjects, prisoners, students and employees.
b. Research on children should be undertaken only if it cannot be conducted equally well on adults. The

purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug the study in children should always be carried out after the phase III clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of the children;

c. Pregnant or nursing women should in no circumstances be the subject of any research unless the research carries no more than minimal risk to the foetus or nursing infant and the object of the research is to obtain new knowledge about the foetus, pregnancy and lactation. Pregnant or nursing women should be part of trials that are designed to protect or advance the health of pregnant or nursing women or foetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable subjects.

d. Selection of subjects should ensure that the benefit and burden is equally distributed.

Documentary Evidences:

a. Checklist for undertaking trial on children.

b. Assent forms in case paediatric submission to ethics committee and approval documented in minutes

c. Institutions policy for conduct of trials on vulnerable population.

d. Confirm if SOP covers this requirement.

e. Policy regarding recruiting employees for the studies.

Outcome: Ethics committee is responsible for protection of special and vulnerable groups.

Onsite assessment: 1] Review of documents at the site 2] Interview

---

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

Interpretation:

a. The SOP should define the role of the legal member of the ethics committee in evaluating the contract to ensure protection of the research participant, indemnification and arbitration. Contract should be reviewed before giving approval for the trial.

Documentary Evidences:

a. The record of opinion of legal representative of the ethics committee in the minutes of meeting

b. Check list for assessing the contract.

c. Confirm if SOP covers this requirement.

Outcome: Rights of subject and research staff are protected.

Onsite assessment: 1] Review of documents at the site 2] Interview

---

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.

Interpretation:

a. The ethics committee should evaluate all the significant amendments to the approved protocol and assess if there is an alteration in the risk benefit ratio.

b. Such formal meetings should be done with prior intimation.

c. Ethics committee will evaluate the changes in the amended informed consent document and investigators brochure.

Documentary Evidences:

a. Amendments submitted.

b. Minutes of meeting demonstrating deliberations and risk assessment of amendments.

c. Confirm if SOP covers this requirement.

Outcome: Evaluation of risks to trial subjects is done in an ongoing basis.

Onsite assessment: 1] Review of documents at the site 2] Interview

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

Interpretation:

a. The ethics committee has procedures for periodic review of the approved proposal through submission of trial updates.

b. The timelines for review should be defined in ethics committee SOP. Review can be done once in three months to six months.

Documentary Evidences:

a. Confirm if SOP covers this requirement.

b. Checklist for documents to be submitted.

c. Documented in minutes of meeting.

d. Record of submission by Investigator.

Outcome: Ethics committee assures continual safety of participants.

Onsite assessment: 1] Review of documents and records at the site 2] Interview

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.

Interpretation:

a. The ethics committee has well defined criteria for quorum as per applicable rules and regulations. Without quorum, the decision cannot be made. For review of each protocol the quorum of Ethics Committee should be at least 5 members with the following representations (a) basic medical scientists (preferably one pharmacologist), (b) clinicians, (c) legal expert, (d) social scientist/ representation of non-governmental voluntary agency / philosopher/ ethicist / theologian or similar person, (e) lay person from the community.

b. The ethics committee ensures that the scientific validity and risk assessment is appropriately done.

c. Chairman or chairman designee should be present during the meeting.

Documentary Evidence:

a. Terms of reference for quorum and role of chairman. Confirm if SOP covers this requirement.

b. Deliberations documented in minutes of the meeting.

c. Written communication to the Principal investigator about the decision by the ethics committee.

Outcome: The decision made is fair and appropriate and quorum meets the regulatory requirement.

Onsite assessment: 1] Review of documents and records at the site 2] Interview

---

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

Interpretation:

a. The ethics committee should be informed of the date of the subject's recruitment

b. Investigator obtains the written ethics committee and regulatory approvals and the clinical trial is registered in www.ctri.nic.in prior to recruitment.

c. Confirm if SOP covers this requirement.

Documentary Evidence:

a. DCGI approval letter

b. EC approval letter

c. www.ctri.nic.in

d. Written communication to the investigator

e. Date of start of recruitment (screening) and signing of consent of the first subject.

Outcome: There is no undue influence in the decision making either by Principal Investigator, Sponsor, and Trial site staffs themselves.

Onsite assessment: 1] Review of documents at the site 2] Interview

---

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

Interpretation:

a. The ethics committee members should declare conflict of interest. Example: if EC member is also the investigator then he/she will declare the conflict of interest to the chairman and will exempt himself/herself from the review process and voting. The chairman will reassess the quorum when any member withdraws from the decision making and this will be recorded in the minutes.

b. The ethics committee members should be aware of the conflict of interest policy.

Documentary Evidence:

a. Confirm if SOP covers this requirement.

b. Template for conflict of interest disclosure form/checklist.

c. Minutes of meeting.

Outcome: There is no undue influence in the decision making either by Principal Investigator, Sponsor, and Trial site staffs themselves.

Onsite assessment: 1] Review of documents at the site 2] Interview

---

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

Interpretation:

a. The ethics committee decisions are based on benefit risk assessment and ethical standards. It has the authority to revert the decision of a proposal initially approved based on the periodic assessment of risk to the trial subject.

Documentary Evidence:

a. Summary of the detailed deliberation should be present in the Minutes of meeting or evidenced through checklist. Minutes of meeting should reflect deliberations on all essential documents as per New Drug & CT Rules 2019

b. Communication records.

c. Confirm if SOP covers this requirement.

Outcome: Risk assessment is a continual process.

Onsite assessment: 1] Review of documents at the site 2] Interview

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

Interpretation:

a. The meetings must demonstrate and document the following deliberations: the presence of full quorum, declaration of the conflict of interest, details of risk-benefit assessment and decision of review (initial, periodic) of the proposal, any changes requested, protocol deviations, serious adverse events and any other relevant discussion/updates. This should be approved and signed by the chairperson/ alternate chairperson.

Documentary Evidence:

a. Confirm if SOP covers this requirement.

b. Minutes of meeting (signed and approved)

Outcome: Ethics committee follows rules and regulations and address subject's safety.

Onsite assessment: 1] Review of documents at the site 2] Interview

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

Interpretation:

a. The ethics committee evaluates the protocol deviations, for analysis and corrective and preventive action taken.

Documentary Evidence:

a. Protocol deviation records

b. Minutes of meeting

c. Documentary evidence of the closure of the deviation or violation

d. Confirm if SOP covers this requirement

Outcome: Research staff adheres to protocol.

Onsite assessment: 1] Review of documents at the site 2] Interview

---

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

Interpretation:

a. Serious adverse events are analysed as per applicable rules and regulations. The ethics committee may suspend/terminate a trial based on the assessment of SAE report if it is determined that the risk is more than the benefit.

b. Reporting timelines are followed as per New Drug & Clinical Trial Rules 2019

c. Recommendations and determinations on compensation for serious adverse events are as per the applicable rules and regulations.

Documentary Evidence:

a. Minutes of meeting.
b. Ethics committee correspondence.
c. Confirm if SOP covers this requirement.

Outcome: Risk assessment and safety of subjects is a continual process.

Onsite assessment: 1] Review of documents at the site 2] Interview

---

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

Interpretation:

a. The ethics committee records all deliberations and decisions made during the formal meetings and this is communicated to the investigator in writing. This is dated and signed either by the chairman or his designee. A copy of the communication is archived in ethics committee file.

Documentary Evidence:

1] Minutes of meeting
2] Records of communication with the principal investigator.
3] Confirm if SOP covers this requirement.

Outcome: There is documentary evidence of communication from Ethics committee to principal Investigator.

Onsite assessment: 1] Review of documents at the site 2] Interview

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.

Interpretation:

a. The ethics committee has procedures in place for regular monitoring of all the proposals approved at the site. Example: This could be done by site visits and review of the following – source documents, the informed consent process, visit details, investigational product storage, case records for SAE management, monitoring reports from the sponsor, DSMB Recommendations, interview with investigator/site staff.

b. The ethics committee has the authority to conduct for-cause audits at the site if there are serious unanticipated problems, non-compliance or protocol deviations.

c. Ethics committee are authorised to communicate and verify with the trial subjects.

Documentary Evidence:

a. Confirm if SOP covers this requirement.

b. Monitoring records

c. Records of action taken if any.

Outcome: Monitoring plan for oversight assures safety of subjects and compliance to applicable rules and regulations.

Onsite assessment: 1] Review of documents at the site 2] Interview

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1.8.2 Adequacy and continuity of consent process shall be ensured

Interpretation:

The ethics committee shall have the authority to monitor the consenting process of a subject being recruited.

Documentary Evidence:

1] Informed consent initial and re-consenting wherever required signed by the subjects

2] Source documents.

3] Confirm if SOP covers this requirement.

Outcome: Monitoring plan for oversight assures rights of subjects and compliance to applicable rules and regulations.

Onsite assessment: 1] Review of documents at the site 2] Interview

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

Interpretation:

a. In case of fraud, scientific misconduct, negligence for-cause assessment can be conducted by the ethics committee. The ethics committee may receive the complaints from the subjects, head of institution or from the investigator.

Documentary Evidence:

a. Records of serious noncompliance in Sponsors monitoring
b. Action taken by ethics committee if any
c. Confirm if SOP covers this requirement

Outcome: Compliance to applicable rules and regulations.

Onsite assessment: 1] Review of documents at the site 2] Interview

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

Interpretation:

a. The ethics committee can suggest any areas that need to be improved based on the findings of their monitoring reports. (For ex- delay in EC approval, Results of the Self-assessment, Root Cause analysis and Corrective & Preventive Action; CAPA)

Documentary Evidence:

a. Communication with the investigator
b. Confirm if SOP covers this requirement

Outcome: Responsibility of ethics committee is to ensure improvement in ethical conduct.

Onsite assessment: 1] Review of documents at the site 2] Interview

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.

Interpretation:

a. Ethics committee conducts self-evaluation. Example: a) ethics committee evaluates the appropriateness of its composition. b) Attendance of members is reviewed. c) Review whether there are adequate resources for ethics committee functioning.

b. There should be at a minimum two periodic reviews per year.

Documentary Evidence:

a. Review process /Checklist

b. Records for evaluation

c. Confirm if SOP covers this requirement.

Outcome: Ethics committee makes them accountable.

Onsite assessment: 1] Review of documents at the site 2] Interview

---

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

Interpretation:

a. The ethics committee should do a root cause analysis to identify if there is a process failure or a system failure.

b. There should be a process and a documented evidence of the corrective and preventive action taken, if required.

Documentary Evidence:

a. Record verification.

b. Confirm if SOP covers this requirement.

Outcome: Ethics committee assesses and improves its functioning.

Onsite assessment: 1] Review of documents at the site 2] Interview

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.

Interpretation:

a. The ethics committee shall have procedures for systematic record keeping as per New Drug & Clinical Trial Rules 2019 of all documentation and communication of the Ethics committee members.

b. Documentation is dated, filed and archived as per the SOP. Confidentiality should be maintained during the retrieval of documents.

c. Procedures should define the storage area for the documents and there should be restricted access with pest-control and fire control.

Documentary Evidence:

a. Confirm if SOP covers this requirement.

b. Records

Outcome: Meets the regulatory requirement for long term follow up.

Onsite assessment: 1] Review of documents at the site 2] Interview

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

Interpretation:

a. Ethics committee should retain all trial related documents after close out and these should be archived as per New Drug & Clinical Trial Rules 2019

Documentary Evidence:

a. Confirm if SOP covers this requirement.

b. Records of Archival and destruction

Outcome: Ensure audit trail.

Onsite assessment: 1] Review of documents at the site 2] Interview

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.

Interpretation:

a. Records should be stored in a way that they can be retrieved for audit and inspection. For this the ethics committee can take the support of the institution.

Documentary Evidence:

a. Policy on record retrieval and record storage.

Outcome: Ensure record retrieval process in place.

Onsite assessment: 1] Review of documents at the site 2] Interview

Abbreviations

1.	AE: Adverse Event
2.	BA/BE: Bioavailability / Bioequivalence
3.	CDSCO: Central Drugs Standard Control Organization
4.	COI: Conflict of Interest
5.	DCGI: Drug Controller General of India
6.	DSMB: Data and 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.	PI: Principal Investigator
14.	SAE: Serious Adverse Events
15.	SOP: Standard Operating Procedures
16.	TOR: Terms of Reference

Glossaries

Table 1 A

Sl No.	List of Terms Used
1	Terms of Reference (TOR)
2	Exempt, expedited review & Full Board Review
3	LAR and Impartial witness with eligibility criteria and hierarchy.
4	Meaning of Monitoring, For Cause audit
5	Definition of Record Retrieval
6	Terminologies used in Causality Assessment
7	Accountability
8	Audit
9	Autonomy
10	Beneficence
11	Case record/report form (CRF)
12	Clinical Research
13	Clinical trial
14	Clinical Trial Registry
15	Cognitive impairment
16	Coercion
17	Collaborative research
18	Compensation
19	Confidentiality
20	Confidentiality Agreement
21	Contract Research Organization (CRO)
22	Custodian
23	Debriefing
24	Deception
25	Distributive Justice
26	Exploitation
27	Independent consultants

Sl No.	List of Terms Used
28	Inducement
29	Informed consent document (ICD)
30	Justice
31	Maleficence
32	Marginalized communities
33	Minimal risk
34	Particularly vulnerable tribal group (PVTG)
35	Pilot studies
36	Post-marketing Surveillance
37	Principal investigator
38	Quorum
39	Research related injury
40	Risk
41	Serious adverse event (SAE)
42	SOP (Standard operating procedure)
43	Sponsor
44	Transparency
45	Undue inducement
46	Unexpected ADR
47	Vulnerability

1. Terms of Reference (TOR): is a Statement of the background, objectives, and purpose of a program, project, or proposal.

Terms of Reference (TOR) can set out the working arrangements for a network and can list vital information about the network, such as its purpose, chair and membership, meeting schedule, level of administrative support, and dispute resolution processes.

Main elements of a TOR are:

- ✓ Role/Purpose, Term, Membership, Roles and Responsibilities, Meetings and Amendment, Modification or Variation
- ✓ Vision, objectives, scope and deliverables (i.e. what has to be achieved)
- ✓ Stakeholders, roles and responsibilities (i.e. who will take part in it)
- ✓ Resource, financial and quality plans (i.e. how it will be achieved)
- ✓ Work breakdown structure and schedule (i.e. when it will be achieved)
- ✓ Success factors, risks and constraints.

2. Types of EC Review

Human subject's research is reviewed by an IRB according to the following categories:

A) Exempt Review: As per acceptable regulations & guidelines

Research can be approved as "exempt" if it is no more than "minimal risk" and fits one of the exempt review categories as defined by federal regulation 45 CFR 46. Studies that may qualify for "Exempt" must be submitted to the IRB for review. Exempt reviews are conducted by a member of IRB staff. They do not require a convened committee meeting.

Exempt Categories are as follows:

Category 1	Education research
Category 2	Surveys, interviews, educational tests, public observations
Category 3	Benign Behavioral Interventions
Category 4	Secondary Research Uses of Identifiable Private Information or Identifiable Bio specimens
Category 5	Federal research or demonstration projects
Category 6	Taste and food quality evaluation studies

B) Expedited Review

Research can be approved as "expedited" if it is no more than "minimal risk" and fits in one of the federally designated expedited review categories. Expedited reviews are conducted by a member of the IRB committee. They do not require a convened committee meeting.

Expedited Categories:

- ✓ Clinical studies of drugs and medical devices only when certain conditions are met.
- ✓ Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture in certain populations and within certain amounts.
- ✓ Prospective collection of biological specimens for research purposes by non-invasive means.
- ✓ Collection of data through non-invasive procedures (not involving general anaesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
- ✓ Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes.
- ✓ Collection of data from voice, video, digital, or image recordings made for research purposes.
- ✓ Research on individual or group characteristics or behaviour or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- ✓ Full-Board Review.
- ✓ Research that does not qualify for expedited or exempt review (presents more than minimal risks to subjects) will receive review at a fully convened IRB committee meeting.

C) Full Board Review

Studies that involve more than minimal risk require review at full board IRB meeting. The research requires approval from a majority of those members. IRB duties are described in the Federal Regulation for Protection of Human Subjects (45 CFR 46).

Examples of Full Board Review

Research involving greater than minimal risk procedures and:

- ✓ clinical procedures with drugs, devices, or biologics, or innovative research into new medical or surgery procedures.
- ✓ taking place internationally (particularly countries with little or no provisions for protection of human subjects) where subjects may be at physical, psychological or legal risk.
- ✓ Disclosure of information that could require mandatory legal reporting (e.g., child/elder abuse, etc.)
- ✓ Deception
- ✓ The EC staff, board member, or designee determines risks are greater than minimal.
- ✓ Vulnerable populations (Children, prisoner, pregnant women and neonates, per federal regulation)

3. Legally Authorized Representative (LAR): A person who will give consent on behalf of a prospective participant who, for either legal or medical reasons, is unable to give consent herself/himself to participate in research or to undergo a diagnostic, therapeutic or preventive procedure as per research protocol, duly approved by the EC.

The LAR may be a parent, grandparent, caregiver who has the legal authority to grant consent on behalf of another who has been invited to participate in research.

Impartial Witness: A literate person, who is independent of the research and would not be unfairly influenced by people involved with the study, who attends the informed consent process if the participant and/or their LAR cannot read, and understand the informed consent form and any other written information supplied to the participant.

LAR Vs impartial Witness

The easiest way to distinguish between the function/use of the Impartial Witness vs the LAR is to think about who really consents. If it is the subject himself who consents, and is able to consent, no LAR is needed. The LAR is only intended for those situations where the subject is unable to consent. For example, in case of underage (not 'of the age of consent') subjects, mentally impaired subjects or trials set in emergency situations. In all the situations where a subject is unable to consent and still included in the trial, it was foreseeable. We don't do trials including vulnerable subjects (and a subject who is unable to consent is by definition vulnerable) unless we have no alternative, and in which case the IRB/IEC has specifically approved of the use of such subjects and of the informed consent procedure used.

A witness never consents on behalf of a subject. A witness, by signing, attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's LAR and that the consent was given freely.

Medical Record Retrieval: This term refers to the process of location a specific file, document or record and then delivering it so it can be used

The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bio availability study or bio equivalence study, as the case may be, for a period of five years after completion of such clinical trial.

Monitoring: It is the act of overseeing the progress of a clinical trial and ensuring that it is conducted, recorded and reported in accordance with the protocol, SOP, GCP and applicable regulatory requirements. It is done by monitor who is the part of the trial.

For-Cause Audit: An audit performed to investigate a specific quality failure or process deviation and/or to prepare for a regulatory inspection. It is done by Independent personnel of a trial like Ethics committee.

Challenge – This refers to the giving of the drug to the patient during the AE or treatment in question. That is, a patient is started today on, say, ampicillin orally. This is the “challenge”.

De-challenge – This refers to the stopping of the drug, usually after an adverse event (AE) or at the end of a planned treatment (e.g. a two-week course of ampicillin). De-challenges may be complete or partial. That is, the drug is fully stopped or decreased in dose and the AE may fully disappear or only partially decrease. The results of the de-challenge can be confusing.

A positive de-challenge – This refers to the AE disappearing after the stopping of the drug. Thus, the AE (which may really be an adverse reaction – AR) of diarrhoea disappeared a day after the patient stopped the ampicillin.

A negative de-challenge – This refers to the AE NOT disappearing after the stopping of the drug. In our example, the diarrhoea continued even after the ampicillin was stopped.

Re-challenge – This refers to the restarting of the same drug after having stopped it, usually for an AE. Re-challenges may also be complete or partial. Thus, the patient may have restarted ampicillin a week later after having stopped it.

A positive re-challenge – This refers to the AE recurring after restarting the drug. To have this occur, the AE had to have previously disappeared after the de-challenge in order for it to restart.

A negative re-challenge – This is the case where the AE does not recur after the drug is restarted.

Accountability: The obligation of an individual or organization to account for its activities, accept responsibility for them and to disclose the results in a transparent manner.

Audit: A systematic and independent examination of research activities and documents to determine whether the review and approval activities were conducted, data recorded and accurately reported as per applicable guidelines and regulatory requirements.

Autonomy: The ability and capacity of a rational individual to make an independently informed decision to volunteer as a research participant.

Beneficence: To try to do good or an action which weighs the risks against benefits to prevent, reduce or remove harm for the welfare of the research participant(s) in any type of research.

Case record/report form (CRF): Case record form or case report form is a printed, optical or electronic document designed to record all the required information in the protocol on each study participant for reporting to the sponsor.

Clinical Research: Research that directly involves a particular person or group of people to study the effect of interventions, or uses materials/data from humans indirectly, such as their behaviour or samples of their tissue for prevention, treatment and diagnosis of a disease condition/health disorder.

Clinical trial: As per amended Schedule Y (2005) of the Drugs and Cosmetics Rules, 1945, a clinical trial refers to a systematic study of new drugs in human subjects to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and /or adverse effect with the objectives determining safety and/or efficacy of a new drug. The academic clinical trial as per GSR 313 (e) dated 16 March 2016 is a clinical trial intended for academic purposes in respect of approved drug formulations for any new indication or new route of administration or new dose or new dosage form.

Clinical Trial Registry: An official platform for registering a clinical trial, such as Clinical Trial Registry-India.

Cognitive impairment: When a person has trouble remembering, learning new things, concentrating, or making decisions that affect their everyday life.

Coercion: An overt or implicit threat of harm to a participant which is intentional to force compliance.

Collaborative research: An umbrella term for methodologies that actively engage researchers, communities and/ or policy makers in the research process from start to finish.

Compensation: Provision of financial payment to the research participants or their legal heirs when temporary or permanent injury or death occurs due to participation in biomedical and health research.

Confidentiality: Keeping information confidential which an individual has disclosed in a relationship of trust and with the expectation that it shall not be divulged to others without permission.

Confidentiality Agreement: Secrecy or non-disclosure agreements designed to protect trade secrets, information and expertise from being misused by those who have learned about them.

Contract Research Organization (CRO): An institution or service organization which represents a sponsor in providing research support/services on a contractual basis nationally or internationally.

Custodian: A person who has responsibility of taking care of or protecting entrusted assets, either biological samples or data.

Debriefing: A process of providing a summary update of a condition or situation to the affected or concerned parties. It is an important ethical consideration in studies involving deception. Such post experimental follow-up is considered beneficial even if no deception is used or there is only minimal risk to participants.

Deception: Occurs when investigators provide false or incomplete information to participants to misleading them to achieve the study objectives and for larger public good. Research employing any type of deception should undergo full committee review.

Distributive Justice: Fair distribution of burden, resources and benefits. In research, it means fair selection of participants.

Exploitation: The action or fact of treating someone unfairly in order to benefit from their participation.

Independent consultants: An expert who gives advice, comments and suggestions to the EC and has no affiliation to the institute or researchers proposing the research protocols. This individual has no voting power for decision making.

Inducement: A motive or consideration that leads one to action or to additional or more effective actions without considering the harm that may occur.

Informed consent document (ICD): Written signed and dated paper confirming a participant's willingness to voluntarily participate in a particular research, after having been informed of all aspects of the research that are relevant for the participant's decision to participate.

Justice: Pertains to fairness in the way people are dealt with, indicating fair selection and distribution of benefits and risks to participants who should be fully apprised about them.

Maleficence: The act of committing harm or a harmful act.

Marginalized communities: A group of people actively separated or excluded from the rest of society.

Minimal Risk: Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of a healthy individual or general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant since it would be undertaken as part of current everyday life.

Particularly vulnerable tribal group (PVTG): These are a special class of tribal groups, classified as such by the Government of India, due to their especially low development indices when compared to other local tribes. These were classified under the Dhebar Commission (1960–1961), so as to better facilitate their growth, at par with other scheduled tribes on a national scale, and help them to get included in mainstream development, while using their indigenous knowledge. They have a pre-agricultural system of existence as mainly hunters with zero or negative population growth, extremely low level of literacy and no written language.

Pilot studies: A pilot study, project or experiment is a small-scale preliminary study conducted in order to evaluate feasibility, time, cost, adverse events and effect size (statistical variability) in an attempt to predict an appropriate sample size and improve upon the study design prior to performance of a full-scale research project.

Post-marketing Surveillance: The practice of monitoring the safety of a pharmaceutical drug or medical device after it has been released on the market. This is an important part of the science of pharmacovigilance.

Principal investigator: An individual or the leader of a group of individuals who initiates and takes full responsibility for the conduct of biomedical health research; if there is more than one such individual, they may be called co-principal investigators/ co-investigators.

Quorum: Minimum number and/or kind of EC members required for decision making during a meeting.

Research related injury: Harm or loss that occurs to an individual as a result of participation in research, irrespective of the manner in which it has occurred, and includes both expected and unexpected adverse events and serious adverse events related to the intervention, whenever they occur, as well as any medical injury caused due to procedures.

Risk: Probability of harm or discomfort to research participants. Acceptable risk differs depending on the conditions inherent in the conduct of research.

Serious adverse event (SAE): An adverse event is serious when the research outcome for the participant is death, life-threatening injury requiring hospitalization, prolongation of hospitalization, significant disability/incapacity, congenital anomaly, or requirement of intervention to prevent permanent impairment or damage.

SOP (Standard operating procedure): Detailed written instructions in a certain format describing all activities and actions to be undertaken by an organization to achieve uniformity in performance of a specific function.

Sponsor: An individual, institution, private company, government or nongovernmental organization from within or outside the country who initiates the research and is responsible for its management and funding.

Transparency: It implies intentional openness, communication, and accountability operating in such a way that it is easy for others to see what actions are performed.

Undue inducement: Offer of disproportionate benefit in cash or kind that compromises judgement which may lead to acceptance of serious risks that threaten fundamental interests.

Unexpected ADR: An adverse reaction, the nature or severity of which is not described in the informed consent/information sheet or the applicable product information, such as an investigator's brochure for the unapproved IP or package insert/summary of product characteristics for an approved product.

Vulnerability: Vulnerability in research pertains to individuals who are relatively or absolutely incapable of protecting their own interests because of personal disability, environmental burdens or social injustice, lack of power, understanding or ability to communicate or are in a situation that prevents them from doing so.

Appendix

Table 1 B

Sl No.	Brief of Appendix	Ref. to Objective Element
1	Format of MOU	1.1.1
2	Format for EC Membership List	1.1.3
3	Sample SOP on SOP	1.2.1
4	SOP templates	1.2.2
5	Eligibility Criteria of EC members-Already done	1.3.1
6	Eligibility Criteria of a GCP Trainer-Needs to be finalized	1.3.5
7	Check list of What Constitutes Conflict of Interest (COI)	1.3.6
8	COI Declaration Form	1.3.6
9	Minutes of meeting Template	1.6.1
10	Checklist for ICF	1.6.4
11	Checklist of Budget	1.6.7
12	Checklist of Contract	1.6.7
13	Risk Benefit Assessment Tool	1.6.8
14	Template on Protocol Deviation	1.7.6
15	Monitoring Checklist	1.8.1
16	Checklist for self-Evaluation of EC	1.9.1
17	Template for Ongoing Trials	1.6.1
18	SAE Reporting Format	1.4.7
19	Causality Assessment-A brief description	1.7.7
20	Scientific Validity of a trial	1.6.2

1. Format of MOU

MEMORANDUM OF UNDERSTANDING

BETWEEN

(Head of the Institute or Designee)

&

(Chairperson of the Ethics Committee)

FOR

Dated: xx xxxxxxxxx

MEMORANDUM OF UNDERSTANDING

- HEADING
- DESCRIPTION
- BACKGROUND
- RESPONSIBILITES OF BOTH THE PARTIES WITH STEP WISE CONDUCT
- BUDGETARY IMPLICATIONS
- PAYMENT SCHEDULE
- EXCLUSIONS
- VALIDITY

Name of the 1st Party By: (Signature) Name: Designation: Date:	Name of the 2nd Party By: (Signature) Name: Designation: Date: xx xxxxxxx,
Witness:	Witness:

TERMS OF REFERENCE FOR BOTH PARTY

FINANCIAL PROPOSAL

Note:

It should be on the letter head of the Institute.

In case of Independent EC, there shall be a separate MOU between each of the hospital/Institute.

2. Format for EC Membership List

Sr. No	Name with age & gender	Qualification	Designation in the Ethics Committee	Roles in IEC	Date of Joining	Past Affiliation with Institution	Present Affiliation with Institution	Member of any Other EC (Yes/No)	If yes, Mention the name of the EC

3. Sample SOP on SOP

Name of the Ethics Committee		
STANDARD OPERATING PROCEDURE	TITLE:	
	DOCUMENT Name & No.:	
	VERSION NUMBER	
	EFFIECTIVE DATE:	
	ISSUE DATE:	
	DOCUMENT CONTROL STATUS:	
	Supersedes: No. of years	Effective Date: Valid Till :
Distribution List:		
Prepared by:		
Signature	Date:	
Reviewed by:		
Signature	Date:	
Approved by:		
Signature	Date:	
Approved by:		
Signature	Following page	Date:
PREPARED BY	**REVIEWED BY**	**APPROVED BY**

SOP

3. Sample SOP on SOP

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4. Ethics Committee-SOP Format

Name & Address

Logo if available

Standard Operating Procedure (SOP)

Title	
Version	
Effective Date	
Earlier Version & Approval Date	
EC Registration No.	
Under Which Institution EC is Constituted	
SOP Status	

Authorized by: **Approved by:**

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7.	Guidelines for submission of SAE Report	
	Category/ Code of clinical trial	

Code	SAEs occurring in clinical trial
CT-1-IND	New Drug - Investigational New Drug (IND) study (where IND is filed in India and is a new chemical entity)
CT-2-Reg	New Drug – Local Clinical Trial– For product approval in India
CT-3-GCT	New Drug – Global Cts
CT-4-rDNA	Biological – Recombinant products (Global CTs, India IND and study for product approval)
CT-5-Vac	Biological – Vaccines (Global CTs, India IND and study for product approval)
CT-6-Oth	Biological – Others (e.g. stem cell studies)
CT-7-Dev	Device study (Global CTs, India IND and study for product approval)
CT-8-Oth	Others

8.	Selection of Special Groups as Research Subject	
9.	Compensation 9.1 Compensation for Participation 9.2 Medical Ancillary Care 9.3 Compensation for SAE/SAE deaths	
10.	Training and Re-orientation of EC members	
11.	EC Training and Self-Assessment	
12.	Format and Templates	

5. Eligibility Criteria of an Ethics Committee Members

Sl. No.	Designation of the EC Member	Roles/Responsibilities
1	**Chairperson/ Vice Chairperson** (optional) **Non-affiliated** **Qualifications -** A well-respected person from any background with prior experience of having served/ serving in an EC	• Conduct EC meetings and be accountable for independent and efficient functioning of the committee • Ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations • Ratify minutes of the previous meetings • In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. • The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting. • Seek COI declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.
2	**Member Secretary/ Alternate Member Secretary (optional)** **Affiliated** **Qualifications –** i. Should be a staff member of the institution ii. Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills. iii. Should be able to devote adequate time to this activity which should be protected by the institution iv. Should be from Healthcare Background	• Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Schedule EC meetings, prepare the agenda and minutes • Organize EC documentation, communication and Archiving • Ensure training of EC secretariat and EC members • Ensure SOPs are updated as and when required • Ensure adherence of EC functioning to the SOPs • Prepare for and respond to audits and inspections • Ensure completeness of documentation at the time of Receipt and timely inclusion in agenda for EC review. • Assess the need for expedited review/ exemption from Review or full review. • Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. • Ensure quorum during the meeting and record discussions and decisions.

3	Basic Medical Scientist(s) Affiliated/ non-affiliated Qualifications – I. Non-medical or medical person with qualifications in basic medical sciences ii. In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist (MD/PhD in Pharmacology) iii. Post graduate in respective area of specialization, adequate experience in respective fields and requisite knowledge and clarity about their role and responsibility as committee member	• Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report • For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.
4	**Clinician(s)** **Affiliated/ non-affiliated** **Qualifications –** i. Should be individual/s with recognized medical qualification, expertise and training ii. Post graduate in respective area of specialization, adequate experience in respective fields and requisite knowledge and clarity about their role and responsibility as committee member	• Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics • Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) • Review medical care, facility and appropriateness of the principal investigator, provision for medical car, Management and compensation. • Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
5	**Legal expert/s** **Affiliated/ non-affiliated** **Qualifications -** i. Should have a basic degree in Law from a recognized university, with experience ii. Desirable: Training in medical law.	• Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research • Interpret and inform EC members about new regulations if any

6	Social scientist/ philosopher/ ethicist/theologian Affiliated/ non-affiliated Qualifications - i. Should be a Graduates/Post Graduates with social/ Behavioral science/ philosophy/ religious qualification and training and/or expertise in local cultural and moral values. ii. Graduates/Post Graduates from an NGO involved in health-related activities	• Ethical review of the proposal, ICD along with the translations. • Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any • Serve as a patient/participant/societal /community representative and bring in ethical and societal concerns.
7	**Lay person(s)** **Non-affiliated** **Qualifications -** i. Literate person from the public or community ii. Has not pursued a medical science/ health related career in the last 5 years iii. May be a representative of the community from which the participants are to be drawn iv. Is aware of the local language, cultural and moral values of the community v. Person having no specific qualification with respect to biomedical research, medicine, or health care. Their primary role is to share insights about the communities from which participants are likely to be drawn	• Ethical review of the proposal, ICD along with translation(s). • Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. • Serve as a patient/participant/ community representative and bring in ethical and societal concerns. • Assess on societal aspects if any.

Note:

At least one of the above members should be a woman. Her role will be commensurate to the appointment that she holds in the Ethics Committee.

6. Eligibility Criteria of a GCP Trainer

A. Individual working in the field of clinical research for 3 years or more.

B. Individual can be in Research Operations, Quality Assurance, Ethics Committee or Regulatory working for a Pharmaceutical company, Medical Device company, Contract Research Organization, Hospital/Research Site or an Educational Institute.

C. Individual should have good knowledge of GCP guidelines, regulations & any other relevant regulatory requirements.

D. Those who are trained in a certified course under NABH, CDSCO, ICMR and other authorized and equivalent bodies.

Note: E certification/E Course will not be accepted as an eligibility Criteria.

7. Checklist of Elements of Conflict of Interest (COI)

Sl. No.	Parameter	Yes	No	Remarks, if any
	For the Subject (Audit purposes)			
1	Is the proposed trial subject a staff member of the PI's department?			
2	Is the proposed trial subject a staff at Institution?			
3	Has the staff member volunteered to take part in the trial?			
	For the PI, Financial (Audit purposes)			
4	In case a hospital staff member at institution has volunteered to take part in the trial, where did he/she get information about the conduct of the trial in the hospital?			
5	Do you or any of your dependents (spouse / children / siblings / parents / parents-in-law) have any shareholdings / stock options / equity interest or has invested in any manner in the pharmaceutical company conducting the trial?			
6	Does the pharmaceutical company conducting the trial provide payment for services like consulting fees or honorarium per participant?			
7	Has the pharmaceutical company conducting the trial promised any intellectual rights from patents, copyrights and royalties from such rights?			
8	Has the pharmaceutical company conducting the trial provided forany agreementwithyouor your dependents (spouse / children / siblings / parents / parents-in- law) that would foresee technology transfer, local training, joint ventures,provision ofhealth care reimbursement, costs of travel and loss of wages and the possible use of a percentage of any royalties for humanitarian purposes?			

9	Haveyoueverservedasanemployeeofthe pharmaceutical company conducting the trial (or any of the group companies of the pharmaceutical company concerned)?			
10	Do you have any plans of serving as an employee of the pharmaceutical company conducting the trial (or any of the group companies of the pharmaceutical company concerned)?			
11	Were you (in any capacity) involved in the drug discovery phase of this molecule which is going for trial?			
12	Have you been involved in any trial for this molecule in any other preceding phase of clinical trials?			

For the PI, non-financial (Audit purposes)

13	Are you serving as a board member or in the capacity of a consultant or advisor to the board members of the pharmaceutical company conducting the trial (or any of the group companies of the pharmaceutical company concerned)?			
14	Do you have any plans to serve as the board member or any other position in decision making capacity of the pharmaceutical company conducting the trial (or any of the group companies of the pharmaceutical company concerned)?			
15	Are you planning the publication of results from this ongoing trial?			
16	Is any trial subject in the proposed study related (family member) to you?			

8. COI Declaration Format

To,

The Chairperson

Name of Ethics Committee:

Project Entitled: ……

Conflict of Interest

I hereby declare that I have no conflict of interest in this trial. I am not on the company's board or I do not have any financial interest in the company. I Am not a PI for this trial.

I have following conflict of interest .....

.....

Name:

Designation:

Signature: Date:

Acceptance from EC Chairperson

The above COI submitted by ....., EC member, has been discussed in the .....Meeting and has been accepted.

Signature & date Name:

9. Minutes of Ethics Committee Meeting Template

Meeting Date:

Next Meeting:

Agenda forwarded to Ethics committee:

Attendance: the table below lists all members of the ethics committee, their role, and attendance.

Sl. No.	Name	Chairperson	Clinician	Basic Medical Scientist	Legal expert	Lay person from community	Philosopher / ethicist / social scientist
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							

9. Minutes of Ethics Committee Meeting Template

Members Absent:

1.

2.

Non-Voting Member:

Alternate Members if any:

Invitees/Subject Experts (Include Affiliation):

Total count:

Quorum:

Definition of Quorum: The quorum is defined as a majority of members, provided the members meet certain specific criteria (not less than 50% and the specific mandatory category) of the members of the total number.

Attendance Notes: movement register (EC members part of the quorum leaving the EC committee meeting in between)

Conflict of Interest:

Approval of Previous Minutes:

Previous Meeting:

Previous Minutes Comments:

Total votes for approval: (Total members voting)

Affirmative:

Negative:

Recusal:

Absent: nonvoting:

Points of Discussion

1. **Discussion of Protocol, initial, amendments**
2. **Discussion on other trial related documents (ICF, Contracts, IB, recruitment strategies including selection of vulnerable subjects)**
3. **Discussion on SAEs, action taken**
4. **Discussion on PV and PD and action taken**
5. **Discussion on CIOMS report**
6. **Training and other matters.**
7. **Any other deemed appropriate**

10. Checklist for Informed Consent Forms (ICF)

Sl. No.	Parameter	Yes	No
1	Purpose of the study		
2	Explanation of what a clinical trial is		
3	Why is the participant being invited to join the trial?		
4	Brief background related to the field of the trial		
5	Details of previous studies and the findings (both good and adverse)		
6	Statement whether the study drug is an approved product or not		
7	Inclusion and Exclusion Criteria		
8	Trial/Visit schedules and details of procedures / drug dosage at each stage		
9	In trials using Placebo, explanation of Placebo and the possibility that the participant may not receive any drug if on a Placebo group		
10	Anticipated Risks and/or Benefits		
11	Compensation paid or not to the Principal Investigator/Staff		
12	Compensation to the participant		
13	Number of participants and number of site		
14	Confidentiality clause on data security/disclosure		
15	Legal rights		
16	Unconditional Right to withdraw anytime without affecting legal rights		
17	Compensation/Coverage for AEs and assurance of adequate and appropriate emergency treatment at no cost to participant		
18	Compensation to participant on incidental expenses		
19	Contact information for participant feedback/queries/complaints		
20	Consent for limits for data usage/period of retention of data		
21	Clauses for termination of trial/ participant from the trial		
22	Clause on new info finding feedback to participant		

23	Protection of minors/vulnerable participants in signing the form		
24	Date & Signature of participant/dependent/witness as applicable		
25	Provision of copy to participant		
26	Version ref. of the ICD		
27	Alternative procedures or treatment is available to the participant.		
28	The Consent form has to be approved by the EC		

11. Checklist for Budget

No. of subjects	
Study duration (months)	
Enrolment period (months)	
Add months for Coordination	
Total study period (months)	

INVESTIGATOR FEES (A+B+C+D = I)			
A) Principal Investigator (Dr._____)			
Consultation Fees	per hour		
	No. of times	Time spent in hrs	Amount in Rs.
Informed consent			
Inclusion/exclusion criteria			
Medical history			
Complete physical examination			
Vital signs			
Efficacy assessments			
Safety assessment			
AE monitoring			
Study drug dosing			
Total PI fees			

B) Consultant consult (Dr. _____)			
Consultation Fees	per hour		
	No. of times	Time spent in hrs	
Medical history			
Complete physical examination			Amount in Rs.

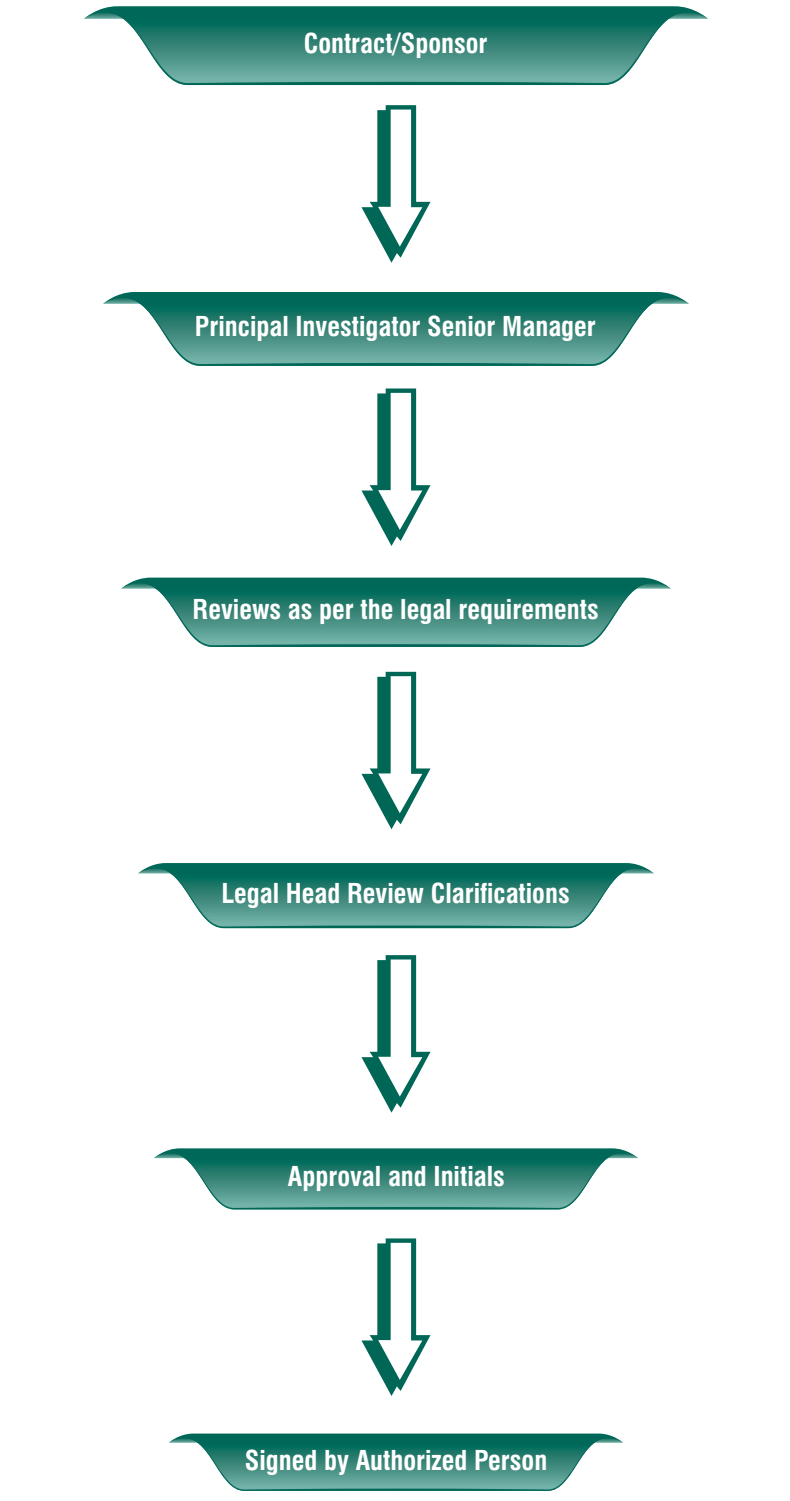
Any other Tests			
Total Consultant fee			

Subject's involvement (II)			
Cost per hour			
	No. of times	Time spent in hrs	Amount in Rs.
Assessment of disease activity			
Assessment of physical activity			
SC injection (An Example)			
PK sampling (An example)			
Total Subject fees			

Clinical Investigations (III)			
	No. of times	Time spent in hrs	Amount in Rs.
Chest X ray			
ECG			
MRI/CT Scan			
Total Clinical Investigations fees			
Lab. Investigations (Central Lab) (IV)			
	No. of times	Time spent in hrs	Amount in Rs.
Phlebotomy			

Centrifugation			
Serum Pregnancy (50% chances)			
Urine pregnancy (50% chances)			
Total Lab Investigations fees			
SUBTOTAL (I+II+III+IV = X)			
Institution Fees @ 10% of Sub-total (Y)			
Cost per patient (X+Y)			
TOTAL fees for 10 patients			
Ethics Committee Fees			
Grand Total- Study Site Budget for Site A			
Grand Total - Study Site Budget for Site A per patient			

PROCESS FOR CONTRACT



12. Checklist for Contracts

1.Parties (Tripartite)		
INSTITUTION, PI and Sponsor's/CRO:		
Urine pregnancy (50% chances SITE : Trial conducted at "CLAUSES:)		
1. Indemnity Clause: (Institution and PI needs to be indemnified)	Yes ☐	No ☐
2. Insurance Policy- Applicable to India:	Yes ☐	No ☐
3. Jurisdiction and Arbitration: Courts of respective states only		
4. Terms of Termination:	Yes ☐	No ☐
5. Checked and approval by Legal Head:	Yes ☐	No ☐
6. Stamp Paper: As Applicable		

CHECKLIST

Number:

Effective Date:

Supersedes:

13. Risk Benefit Assessment Tool (select Whichever Is Applicable And Identify The Class With Reason)

HIGH RISK/LOW BENEFIT (CLASS-A)

Risks:

- Completely new drug/formulation
- Highly Toxic substances
- Safety / Effectiveness not established through earlier studies
- High incidence of SAEs / side effects in prelim studies
- Inadequate or no risk AE handling mechanisms
- High data disclosure and data leakage possibilities
- Affects large no. of participants
- Violation legal / statutory regulations
- Inadequate project documentation
- Inadequate PI / Staff expertise
- New / untried procedures
-

Benefits:

- ☞ Cost of treatment/drug borne by participant
- ☞ Replaces current drugs with no extra benefits either treatment wise or cost wise
- ☞ Short term relief as opposed to long term action
- ☞ No post trial alternatives

HIGH RISK/HIGH BENEFIT (CLASS-B)

Risks:

- Completely new drug/formulation
- Highly Toxic substances
- Safety / Effectiveness not established through earlier studies
- High incidence of SAEs / side effects in prelim studies
- Inadequate or no risk AE handling mechanisms
- High data disclosure and data leakage possibilities
- Affects large no. of participants
- Violation legal/statutory regulations
- Inadequate project documentation
- Inadequate PI / Staff expertise
- New/untried procedures

Benefits:

- Completely new cure
- Preventive for life i.e. Vaccinations
- Significant improvement over existing cures/treatments
- Minimal side effects vis a vis existing treatments
- Elimination of disease rather than temporarily curative
- Significant reduction in treatment costs/mode (ex. Pill vs surgery)
- Extension of benefits / availability of treatment post trial
- Benefits large no. of participants

LOW RISK / LOW BENEFIT (CLASS-D) Risks:

- Proven / Acceptable toxicity
- Proven safety and efficacy
- Drug / formulation a variation of approved drug / class of drugs
- SAEs indicate minor/acceptable reactions, side effects
- No drug but only data analysis
- Minimal data disclosure / leakage possibilities
- Minimal risk to legal / statutory regulations
- Standard operating / surgical procedures

Benefits:

- Cost of treatment/drug borne by participant
- Replaces current drugs with no extra benefits either treatment wise or cost wise
- Short term relief as opposed to long term action
- No post trial alternatives

LOW RISK/HIGH BENEFIT (CLASS-C) Risks:

- Proven / Acceptable toxicity
- Proven safety and efficacy
- Drug / formulation a variation of approved drug / class of drugs
- SAEs indicate minor / acceptable reactions , side effects
- No drug but only data analysis
- Minimal data disclosure / leakage possibilities
- Minimal risk to legal / statutory regulations

Standard operating / surgical procedures

Benefits :

- Completely new cure
- Preventive for life i.e. Vaccinations
- Significant improvement over existing cures / treatments
- Minimal side effects vis a vis existing treatments
- Elimination of disease rather than temporarily curative
- Significant reduction in treatment costs / mode (ex. Pill vs surgery)
- Extension of benefits / availability of treatment post trial
- Benefits large no. of patients

14. Template on Protocol Deviation

Name of IRB / IEC: _____

SPONSOR: _____

INVESTIGATOR (S): _____

PROTOCOL TITLE: _____

Notifiable to IRB (Y/N) _____ if Yes, Date of notification _____
[If yes fill 'Notification of Protocol Deviation/Violation Form' and submit to IRB]

Describe the Deviation/ Non-Compliance:

This Deviation / Non- Compliance:

[ ] **Does not** increase the risks to participants in the approved protocol

[ ] **Does** increase the risks to participants in the approved protocol

Was the deviation due to:

[ ] Investigator error [ ] Subject error [ ] Circumstance [ ] Other(s)

Explain why the deviation occurred:

Explain what is being done to prevent future occurrence:

1. Was/Were participant(s) adversely affected by the deviation?
   If yes, explain (submit an adverse event reporting form): Yes [ ] No [ ]
2. Was / Were the participant(s) informed of the deviation / Non-Compliance?
   If no, explain: Yes [ ] No [ ]
3. Will the participant(s) remain in the study? Yes [ ] No [ ]
4. Will the research study continue? Yes [ ] No [ ]

Prepared by & Date _____ (DD/MM/YY)

Reviewed by & Date _____ (DD/MM/YY)

Investigator's Signature & Date_____ (DD/MM/YY)

15. Template of monitoring Checklist

AUDIT REPORT FOR CLINICAL TRIAL FROM START POINT TO END END POINT					
	Trial - 1	Trial - 2	Trial - 3	Trial - 4	Compliance level
Sponsor Name :					
Protocol reference number :					
Study subject reference:					
Name of Principle Investigator :					
Name of Study coordinators :					
Date:					

I. Research office

A. Document Management

Sl. No	Check Parameters	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	%
1	All documents exist in the Trial Master file is as per the index																
2	All documents is in the same order mentioned in the index													0	0	0	0
3	All documents are easily traceable													0	0	0	0
4	All documents are labelled for easy identification													0	0	0	0
5	informed consent exist for the research subject													0	0	0	0
6	Documented procedures / SOPs exist for all the activities of research													0	0	0	0
Compliance		**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

B Verification of Participant consent

a. The informed consent contains the fallowing Basic Elements of disclosure and is verified for completeness

Sl. No	Check Parameters	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	%
1	A statement that the study involves research													0	0	0	0
2	An explanation of the purposes of the research													0	0	0	0
3	The expected duration of the subject's participation													0	0	0	0
4	A description of the procedures to be followed													0	0	0	0
5	Identification of any procedures which are experimental (may be omitted if there are none)													0	0	0	0
6	A description of any reasonably foreseeable risks or discomforts to the subject (may be omitted if there are none)													0	0	0	0
7	A description of any benefits to the subject or to others which may reasonably be expected from the research (may be omitted if there are none)													0	0	0	0
8	A disclosure of appropriate alternative procedures or course of treatment, if any, that might be advantageous to the subject (may be omitted if there are none).													0	0	0	0

Sl. No	Check Parameters	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	%
9	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (may be omitted if confidentiality will not be maintained).													0	0	0	0
10	A statement that notes the possibility that the Food and Drug Administration may inspect the records. (May be omitted for research that is not subject to FDA regulations).													0	0	0	0
11	An explanation as to whether compensation is available if injury occurs. (May be omitted if the research involves no more than minimal risk.)													0	0	0	0
12	If compensation is available when injury occurs, an explanation as to what it consists of or where further information may be obtained. (May be omitted if the research involves no more than minimal risk.)													0	0	0	0
13	An explanation as to whether any medical treatments are available if injury occurs. (May be omitted if the research involves no more than minimal risk.)													0	0	0	0
14	If medical treatments are available when injury occurs, an explanation as to what it consists of or where further information may be obtained. (May be omitted if the research involves no more than minimal risk.)													0	0	0	0

Sl. No	Check Parameters	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	%
15	An explanation of whom to contact for answers to pertinent questions about the research.													0	0	0	0
16	An explanation of whom to contact for answers to pertinent questions about the research participants' rights.													0	0	0	0
17	An explanation of whom to contact in the event of a research-related injury to the participant. (Note: MUST be included for federally-funded research; may NOT be omitted just because the research involves no more than minimal risk. For non-federally funded research equivalent protections may be used)													0	0	0	0
18	A statement that participation is voluntary and the signature from the subject / LAR for the same.													0	0	0	0
19	A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.													0	0	0	0
20	A statement that the participant can discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.													0	0	0	0

Compliance	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

C. Informed consent contains the fallowing additional elements of disclosure and is verified for completeness.

Sl. No	Check Parameters	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	%
1	A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable.													0	0	0	0
2	A statement that if the participant is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or foetus, which are currently unforeseeable.													0	0	0	0
3	Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.													0	0	0	0
4	Any additional costs to the participant that may result from participation in the research.													0	0	0	0
5	The consequences of a participant's decision to withdraw from the research.													0	0	0	0
6	Procedures for orderly termination of participation by the participant.													0	0	0	0
7	A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant.													0	0	0	0

Sl. No	Check Parameters	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	%
8	The approximate number of participants involved in the study.													0	0	0	0
9	The amount and schedule of all payments for all participants													0	0	0	0
Compliance		**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

D. Study subject safety

Sl. No	Check Parameters	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	%
1	All Adverse events are documented													0	0	0	0
2	All Adverse events are notified to sponsors													0	0	0	0
3	All SAE are documented													0	0	0	0
4	All SAE are notified to sponsors within 24 hours													0	0	0	0
5	All SUSAR are notified to sponsors within 24 hours													0	0	0	0
6	All SAE are notified to Ethics Committee within 7 days													0	0	0	0
7	All SUSAR are notified to Ethics Committee within 7 days													0	0	0	0
8	whether research subject fits in for the study as per the inclusion criteria													0	0	0	0
Compliance		**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

II Ethics Committee

A Minutes of meeting

a. Documentation of attendance at the meeting:

Sl. No	Check Parameters	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	%
	Check the box to indicate the requirement is met:													0	0	0	0
1	names of members present													0	0	0	0
2	names of members absent													0	0	0	0
3	names of alternates and which member they are replacing													0	0	0	0
4	names of staff present													0	0	0	0
5	inclusion of consultants or permanent members, with competence to review of issues that require additional expertise													0	0	0	0
6	researchers or other guests present													0	0	0	0
	Compliance	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

b Documentation of Quorum: India

Sl. No	Check Parameters	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	%
	Check the box to indicate the requirement is met:													0	0	0	0
1	statement that a quorum is the majority of members present													0	0	0	0
2	a lay (non-scientist) person from the community.													0	0	0	0
3	a basic medical scientist.													0	0	0	0
4	a non-affiliated member*													0	0	0	0
5	a clinician (if research falls under FDA regulations, the physician must be licensed)													0	0	0	0
6	a legal expert													0	0	0	0
7	a philosopher, ethicist, theologian (or similar person), social scientist, representative of a non-government agency																

Compliance	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

d. Documentation of conflict of interest

Sl. No	Check Parameters	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	%
	Check the box to indicate the requirement is met:													0	0	0	0
1	Minutes list criteria for conflicts of interest that members should declare													0	0	0	0
2	When members report conflicts, they do not participate in discussion or vote, except to provide information to the IRB													0	0	0	0
3	Minutes list criteria for conflicts of interest that organization should declare													0	0	0	0
4	When organization report conflicts, they do not submit the study documents to IRB but will submit to other Ethics committee													0	0	0	0

Compliance	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

e. Documentation of whether files contain information necessary to reconstruct a complete history of the study

Sl. No	Check Parameters	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	%
	Check the box to indicate that all EC records for each study include:																
1	Protocols or research plans													0	0	0	0
2	Investigator brochure, if any													0	0	0	0
3	Scientific evaluations provided by the Scientific Review Committee													0	0	0	0
4	Recruitment materials													0	0	0	0
5	Consent documents													0	0	0	0
6	All requests to modify or amend the study													0	0	0	0
	Compliance	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

f. Additional information for continuing review of ongoing studies

Sl. No	Check Parameters	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	%
	Check the box to indicate that EC records also include the following additional information at time of continuing review:																
1	Progress reports submitted by Researchers													0	0	0	0
2	Records of continuing review activities													0	0	0	0
3	Data and safety monitoring reports, if any													0	0	0	0
4	Modifications to previously approved research													0	0	0	0
5	Unanticipated problems involving risks to participants or others													0	0	0	0
6	Documentation of non-compliance (whether there is non-compliance in fact, whether non-compliance is serious, whether non-compliance is continuing)													0	0	0	0
7	Significant new findings													0	0	0	0
8	All correspondence between the EC and Researchers (e.g., approval letters and other correspondence)													0	0	0	0

Compliance	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

g. Review of Records

Sl. No	Check Parameters	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	%
1	Is the initial IRB approval letter on file													0	0	0	0
2	Is the study undergone continuning review													0	0	0	0
3	Was the status report submitted on time													0	0	0	0
4	Does all amendments have ECs documented approval													0	0	0	0
5	If there been a premature termination / suspension of the study whether reason for the same is documented													0	0	0	0
6	Is this a Schedule Y regulated study													0	0	0	0
7	Is there a DCGI approval													0	0	0	0
8	Is there a import certificate for the investigational producte if the same is from outside the country													0	0	0	0
9	Whether recruitment methods and materials approved by EC													0	0	0	0
10	Whether pre-screening method approved by EC													0	0	0	0
Compliance		**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

16. Self-Evaluation of Ethics Committee-Template

Sl. No.	Check Parameters	Method of evaluation	Chairman	Member Secretary	Member 1	Member 2	Member 3	Member 4	Check Parameters	Member 5	Member 6	Member 7	Member 8
1	Qualification	Checking the CV	Available at EC office records	Available at EC office records	Available at EC office records	Available at EC office records	Available at EC office records	Available at EC office records	Qualification	Available at EC office records	Available at EC office records	Available at EC office records	Available at EC office records
2	Experience	Checking the CV	Available at EC office records	Available at EC office records	Available at EC office records	Available at EC office records	Available at EC office records	Available at EC office records	Experience	Available at EC office records	Available at EC office records	Available at EC office records	Available at EC office records
3	Awareness of Responsibilities and handling during the meeting	Interview	Aware of responsibilities	Aware of responsibilities	Aware of responsibilities	Aware of responsibilities	Aware of responsibilities	Aware of responsibilities	Awareness of Responsibilities and handling during the meeting	Aware of responsibilities	Aware of responsibilities	Aware of responsibilities	Aware of responsibilities
a	Chairing the session	Interview	Is aware the process and responsibilities of chairng the EC meetings	Is aware the process and responsibilities of chairng the EC meetings in the absence of Chair person	Not applicable	Not applicable	Not applicable	Not applicable	Chairing the session	Not applicable	Not applicable	Not applicable	Not applicable
b	minutes of meeting	Interview	Is aware that he needs to approve the minutes of meeting	is aware the need of approve the minutes in the absense of chairperson	is aware that need to go through the minutes to cross check whether all points discussed are covered	is aware that need to go through the minutes to cross check whether all points discussed are covered	is aware that need to go through the minutes to cross check whether all points discussed are covered	is aware that need to go through the minutes to cross check whether all points discussed are covered	minutes of meeting	is aware that need to go through the minutes to cross check whether all points discussed are covered	is aware that need to go through the minutes to cross check whether all points discussed are covered	is aware that need to go through the minutes to cross check whether all points discussed are covered	is aware that need to go through the minutes to cross check whether all points discussed are covered

	Check Parameters	Method of evaluation	Chairman	Member Secretary	Member 1	Member 2	Member 3	Member 4	Check Parameters	Member 5	Member 6	Member 7	Member 8
c	Quorum for the meeting	Interview	Is aware about the requirement of the minimum quorum and its importance for holding meetings	Is aware about the requirement of the minimum quorum and its importance for holding meetings	Is aware about the requirement of the minimum quorum and its importance for holding meetings	Is aware about the requirement of the minimum quorum and its importance for holding meetings	Is aware about the requirement of the minimum quorum and its importance for holding meetings	Is aware about the requirement of the minimum quorum and its importance for holding meetings	Quorum for the meeting	Is aware about the requirement of the minimum quorum and its importance for holding meetings	Is aware about the requirement of the minimum quorum and its importance for holding meetings	Is aware about the requirement of the minimum quorum and its importance for holding meetings	Is aware about the requirement of the minimum quorum and its importance for holding meetings
d	conflict of interest	Interview	Is aware that the members must declare the conflict of interest. After the AAHRPP site visit, is also aware that the institution should declare the conflict of interest	Is aware that the members msut declare the conflict of interest. After the AAHRPP site visit, is also aware that the institution should declare the conflict of interest	Is aware the need and importance of declaring the conflict of interest before the EC meeting	Is aware the need and importance of declaring the conflict of interest before the EC meeting	Is aware the need and importance of declaring the conflict of interest before the EC meeting	Is aware the need and importance of declaring the conflict of interest before the EC meeting	conflict of interest	Is aware the need and importance of declaring the conflict of interest before the EC meeting	Is aware the need and importance of declaring the conflict of interest before the EC meeting	Is aware the need and importance of declaring the conflict of interest before the EC meeting	Is aware the need and importance of declaring the conflict of interest before the EC meeting
e	Attendence for the meetings	Interview	good	good	good	good	good	good	Attendence for the meetings	good	good	good	good
f	Participation in the meeting	Interview	good	good	good	good	good	good	Participation in the meeting	good	good	good	good

	Check Parameters	Method of evaluation	Chairman	Member Secretary	Member 1	Member 2	Member 3	Member 4	Check Parameters	Member 5	Member 6	Member 7	Member 8
4	Pre meeting preparedness review Interview	Interview	Is aware on preparedness before the meeting	Is aware on preparedness before the meeting	Is aware on prepared ness before the meeting	Is aware on prepared ness before the meeting	Is aware on prepared ness before the meeting	Is aware on prepared ness before the meeting	Pre meeting preparedness review	Is aware on prepared ness before the meeting	Is aware on prepared ness before the meeting	Is aware on prepared ness before the meeting	Is aware on prepared ness before the meeting
a	Awareness of protocols by members	Interview	Is aware of protocols and there importance	Is aware of protocols and there importance	Is aware of protocols and there importan ce	Is aware of protocols and there importan ce	Is aware of protocols and there importan ce	Is aware of protocols and there importan ce	Awareness of protocols by members	Is aware of protocols and there importan ce	Is aware of protocols and there importan ce	Is aware of protocols and there importan ce	Is aware of protocols and there importan ce
b	Timeliness for submission of protocols by EC office	Interview	yes, is receiving the protocols prior to 3 weeks of EC meetings	yes, is receiving the protocols prior to 3 weeks of EC meetings	yes, is receiving the protocols prior to 3 weeks of EC meetings	yes, is receiving the protocols prior to 3 weeks of EC meetings	yes, is receiving the protocols prior to 3 weeks of EC meetings	yes, is receiving the protocols prior to 3 weeks of EC meetings	Timeliness for submission of protocols by EC office	yes, is receiving the protocols prior to 3 weeks of EC meetings	yes, is receiving the protocols prior to 3 weeks of EC meetings	yes, is receiving the protocols prior to 3 weeks of EC meetings	yes, is receiving the protocols prior to 3 weeks of EC meetings
c	Preparedness for the meeting	Interview	Is aware about importance of going thorough the protocols before the meetings	Is aware about importance of going thorough the protocols before the meetings	Is aware about importan ce of going thorough the protocols before the meetings	Is aware about importan ce of going thorough the protocols before the meetings	Is aware about importan ce of going thorough the protocols before the meetings	Is aware about importan ce of going thorough the protocols before the meetings	Preparedness for the meeting	Is aware about importan ce of going thorough the protocols before the meetings	Is aware about importan ce of going thorough the protocols before the meetings	Is aware about importan ce of going thorough the protocols before the meetings	Is aware about importan ce of going thorough the protocols before the meetings

	Check Parameters	Method of evaluation	Chairman	Member Secretary	Member 1	Member 2	Member 3	Member 4	Check Parameters	Member 5	Member 6	Member 7	Member 8
5	Awareness on Internal audit	Interview	Is aware the process to be followied during the internal audit	Is aware the process to be followied during the internal audit	Is aware the process to be followied during the internal audit	Is aware the process to be followied during the internal audit	Is aware the process to be followied during the internal audit	Is aware the process to be followied during the internal audit	Awareness on Internal audit	Is aware the process to be followied during the internal audit	Is aware the process to be followied during the internal audit	Is aware the process to be followied during the internal audit	Is aware the process to be followied during the internal audit
6	Awareness on consenting process	Interview	Is completely aware of consenting process	Is completely aware of consenting process	Is completely aware of consenting process	Is completely aware of consenting process	Is completely aware of consenting process	Is completely aware of consenting process	Awareness on consenting process	Is completely aware of consenting process	Is completely aware of consenting process	Is completely aware of consenting process	Is completely aware of consenting process
7	Knowledge and awareness after NABH Site visit or GCP course	Interview	Knowledge and awareness has improved	Knowledge and awareness has improved	Knowledge and awareness has improved	Knowledge and awareness has improved	Knowledge and awareness has improved	Knowledge and awareness has improved	Knowledge and awareness after NABH Site visit or GCP course	Knowledge and awareness has improved	Knowledge and awareness has improved	Knowledge and awareness has improved	Knowledge and awareness has improved

17. Template for Ongoing Trials

Details of the Ongoing Trial List														
Sl No.	Name of the Trial	Objective of the Trial	Name of the PI and Co-I	Phase of the study	Date of Start of Study	Date of DCGI approval	Date of EC approval	No. of patients recruited	Unicentric /Multicentric	Trial site Names	Hospital Reference No. /Hospital code 11	Proposed Sample Size	Proposed Study close out date	Site Sample Target	No. of SAEs/ SAEs death

18. SAE Reporting Format

NABH SAEs/SAE Death Reporting Format											
Sl No	Protocol Name & No.	CTRI No.	SAE onset date (DD/ MM/ YYYY)	SAE Stop Date (DD/ MM/ YYYY)	SAE Term a) Death, life-threatening injury requiring hospitalization b) prolongation of hospitalization c) significant disability/incapacity, congenital anomaly d) requirement of intervention to prevent permanent impairment or damage	Death if any	Details of the Cause	DCGI Decision	Compensation Paid (Y/N)	If Yes, provide the evidence	if No, then Steps taken by the Ethics Committee

19. Guideline for Causality Assessment2

Causality term	Assessment Criteria
Certain	Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an • objective and specific medical disorder or a recognised pharmacological • phenomenon) • Re-challenge satisfactory, if necessary
Probable / Likely	Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Re-challenge not required
Possible	Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional / Unclassified	Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable /Unclassifiable	Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified

Summarizing Causality Assessment

Category	Time Relationship	Other Cause (Disease/Drug/Lab/abnormality)	Positive De-challenge	Positive Re-challenge
Certain	Yes	No	Yes	Yes
Probable	Yes	Possibly no (unlikely to be due to other cause)	Yes	No
Possible	Yes	Possibly Yes (May be due to other cause)	No	No
Unlikely	Doubtful	Most Probably due to other cause	No	No

20. Scientific Validity of the Trial

Date:

Proposed Title/Protocol No.

Principal investigator

Co-Investigator

Supporting Institution/agency:

If Non ICMR, kindly mention the name:

Project Status:	New	☐	Revised	☐
Review :	Regular	☐	Interim	☐

Date of Review :

1. Research Design

Scientifically sound enough to expose subject's to risk :	Yes	☐	No	☐
Relevant to contribute to further knowledge :	Yes	☐	No	☐
Of National Importance :	Yes	☐	No	☐

2. Risks

Is there any physical/social/psychological risk/discomfort?	Yes	☐	No	☐
Is the overall risk/benefit ratio	Acceptable	☐	Non-Acceptable?	☐

3. Benefits

I.	Direct :	☐	Reasonable	☐	Undue	☐	None	☐
ii.	Indirect :	☐	Improvement in Science/Knowledge			☐	Any other	☐

4. Subject Selection

I.	Inclusion/Exclusion Criteria addressed?	Yes	☐	No	☐
ii.	Vulnerable Subjects (Woman, Child, mentally challenged Seriously ill, terminally ill, economically or socially backward and health volunteers) adequately protected?	Yes	☐	No	☐
iii.	Special group subjects (Captives, Students, nurses & dependent staff) adequately protected	Yes	☐	No	☐

5. Privacy & Confidentiality maintained :	**Yes**	☐	**No**	☐
Patient Information Sheet :	Adequate	☐	In adequate	☐
Consent form addressed adequately :	Yes	☐	No	☐
Compensation, (if applicable) addressed adequately?	Yes	☐	No	☐
Is there a conflict of interest?	Yes	☐	No	☐
If yes	Acceptable	☐	Unacceptable	☐
6. Budget	**Appropriate**	☐	**Inappropriate**	☐

7. Decision of Review:

Recommended	☐	Recommended with Suggestions	☐
Revision	☐	Rejected	☐

NATIONAL ACCREDITATION BOARD FOR HOSPITALS & HEALTHCARE PROVIDERS

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