

Institutional Ethics Committee Of KLE Academy of Higher Education and Research

(Nehru Nagar, J.N.Medical College campus, Belagavi 590010, India)
KLES Dr.Prabhakar Kore Hospital, Belgaum-590010, Karnataka State India
t: 0831-2470400 www.kledeemeduniversity.edu.in mail: kleclinicalresearch@gmail.com

FORM NO: 44

Format of IEC Meeting Minutes

Type of Meeting: Full Board Meeting

Venue: IEC office, Conference Room, KLES Dr.PK Hospital and MRC, Belagavi-10

Date of issuance:

Attendance:

Present:

- Member 1 (name, position, science/non-science, affiliated/non-affiliated, male/female)
- Member 2 (name, position, science/non-science, affiliated/non-affiliated, male/female)
- Member 3 (name, position, science/non-science, affiliated/non-affiliated, male/female)
- Member 4 (name, position, science/non-science, affiliated/non-affiliated, male/female)
- Member 5 (name, position, science/non-science, affiliated/non-affiliated, male/female)

Absent:

- Member 1 (name, position, science/non-science, affiliated/non-affiliated, male/female)
- Member 2 (name, position, science/non-science, affiliated/non-affiliated, male/female)
- Member 3 (name, position, science/non-science, affiliated/non-affiliated, male/female)
- Member 4 (name, position, science/non-science, affiliated/non-affiliated, male/female)
- Member 5 (name, position, science/non-science, affiliated/non-affiliated, male/female)

Subject Expert/Intendent Consultant:

Member 1 -Name, Designation -Department-Affiliation, male/female

Others:

Staff (name, position)

Guest (name, position)

1. CALL TO ORDER

<Title, First name, surname> Chair, called this meeting to order at. Time>

2. DETERMINATION OF QUORUM

Quorum was declared with the presence of members, inclusive of the presence of medical, non-medical/lay, noninstitutional, and female members, as confirmed by the Member Secretary, .

3. DISCLOSURE OF CONFLICT OF INTEREST

<Title, surname of chair>called for disclosure of Conflict of Interest (COI) in the Protocols scheduled for deliberation in the meeting. The following member/s inhibited from participation in the deliberations during the full board meeting for the following reasons:

<Title, Name, surname > as Investigator for the study entitled, "TITLE" (PROTOCOL NUMBER)

4. APPROVAL OF THE AGENDA

<Title, surname of chair > presided over the discussion of the agenda of the meeting for (Date of current meeting). The agenda was corrected during the discussion and approved as amended.

5. APPROVAL OF THE MINUTES OF THE LAST MEETING:

- 5.1. Corrections in the Meeting Minutes
- 5.2. Approval of the Meeting Minutes
- 5.3. Matters Arising from the Minutes of the Last Meeting requiring EC action

6. PROTOCOL REVIEW:

6.1. FULL BOARD REVIEW

6.1.1. Protocols for Initial Review

Protocol Code	
Submission date	
Protocol Title	

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Principal Investigator	
Reviewers	
Sponsor or CRO	
Quorum status	
Conflict of Interest	
Assessment of Scientific Issues	<ol style="list-style-type: none"> 1. Rationale and literature review 2. Objectives/Expected output 3. Research/Study design 4. Study population, sampling design, and sample size 5. Inclusion criteria 6. Exclusion criteria 7. Withdrawal criteria 8. Control arms (placebo or less effective intervention, if any) 9. Study procedures and tools 10. Data management and analysis
Assessment of Ethical Issues	<ol style="list-style-type: none"> 1. Risks 2. Benefits 3. Vulnerability
Assessment of Informed Consent Issues	<ol style="list-style-type: none"> 1. Completeness of patient information sheet (PIS) and informed consent form (ICF) 2. Language and translation of PIS and ICF 3. Voluntary participation 4. Insurance and medical care 5. Cost, compensation, and reimbursement 6. Privacy and confidentiality 7. Assent and parental consent 8. Informed consent process
Assessment of the Qualification of the Investigator	<ol style="list-style-type: none"> 1. Expertise 2. Training 3. Conflict of interest
Conclusion and Recommendations	
Action Taken	<ol style="list-style-type: none"> 1. Approved – with or without suggestions or comments; 2. Revision with minor modifications/amendments 3. Revision with major modifications for resubmission 4. Disapproved
Approval Expiration Date (if applicable)	
Frequency of Continuing Review (in case of approval and minor revision)	

6.1.2. Protocols for Modification or Resubmissions

Protocol Code	
Re-Submission date	
Protocol Title	
Principal Investigator	

Reviewers	
Sponsor or CRO	
Quorum status	
Conflict of Interest	
Assessment of PI Response to Initial Review	
Conclusion and Recommendations	
Action Taken	<ol style="list-style-type: none"> 1. Approved 2. Minor modification to the amendment, 3. Major modification to the amendment 4. Disapprove Expedited review at the level of the Member Secretary;
Approval Expiration Date	
Frequency of Continuing Review (in case of approval and minor revision)	

6.1.3. Amendments

Protocol Code	
Approval date	
Submission date	
Protocol Title	
Principal Investigator	
Reviewers	
Sponsor or CRO	
Time allotment	
Quorum status	
Conflict of Interest	
Assessment of Amendment	
Conclusion and Recommendations	
Action Taken	<ol style="list-style-type: none"> 1. Approved 2. Minor modification to the amendment, 3. Major modification to the amendment 4. Disapprove

6.1.4. Protocol Non-Compliance (Deviation or Violation) Reports

Protocol Code	
Approval date	
Report date	
Protocol Title	
Principal Investigator	
Reviewers	
Sponsor or CRO	

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Quorum status	
Conflict of Interest	
Assessment of Protocol Non-Compliance Report	
Conclusion and Recommendations	
Action Taken	Decision No further action required; Request information, Recommend further action

6.1.5. SAE Reports

SAE Reports		
Protocol Code		
Approval date		
Report date		
Protocol Title		
Principal Investigator		
Reviewers		
Sponsor or CRO		
Quorum status		
Conflict of Interest		
Assessment of SAE	Submission Date	
	Date of SAE	
	Onsite or offsite	
	Country (if offsite)	
	SUSAR or Non-SUSAR	
	Related or Non-Related to the Study	
	SAE Status	
Conclusion and Recommendations		
Action Taken	Decision No further action required; Request information, Recommend further action	

6.1.6. Requests, Queries, and Complaints

Protocol Code	
Approval date	
Application date	
Protocol Title	
Principal Investigator	
Reviewers	
Sponsor or CRO	
Assessment of Request, Query or Complaint	
Conclusion and Recommendations	
Action Taken	No further action required; Request information, Recommend further action
Conclusion and Recommendations	

6.1.7. Site Visit Reports

Protocol Code	
Protocol Approval date	

Protocol Title	
Site Visit date	
Principal Investigator	
Reviewers	
Sponsor or CRO	
Quorum status	
Conflict of Interest	
Assessment of Site Visit Report	
Action Taken	No further action required; Request information, Recommend further action
Conclusion and Recommendations	

6.1.8. Study Termination

Protocol Code	
Protocol Approval date	
Application date	
Protocol Title	
Principal Investigator	
Reviewers	
Sponsor or CRO	
Quorum status	
Conflict of Interest	
Assessment of Risks from Study Termination	
Action Taken	No further action required; Request information, Recommend further action
Conclusion and Recommendations	

6.1.9. Continuing and Progress Reports

Protocol Code	
Protocol Approval date	
Application date	
Protocol Title	
Principal Investigator	
Reviewers	
Sponsor or CRO	
Quorum status	
Conflict of Interest	
Assessment of Continuing and Progress Report	
Action Taken	No further action required; Request information, Recommend further action
Conclusion and Recommendations	

6.1.10. Final Reports

Protocol Code	
Protocol Approval date	
Application date	
Protocol Title	
Principal Investigator	

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Reviewers	
Sponsor or CRO	
Quorum status	
Conflict of Interest	
Assessment of Final Report	
Action Taken	No further action required; Request information, Recommend further action
Conclusion and Recommendations	

5. OTHER MATTERS:

6. ADJOURNMENT: This meeting was adjourned at

Prepared by	SECRETARIAT STAFF-Name	Date and signature
Checked by	Member Secretary-Name	Date and signature
Approved by	Chairperson-Name	Date and signature