

FORM NO: 43

Format of an Agenda

Type of Meeting: Full Board Meeting

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

Date of issuance:

To,

NOTICE OF MEETING:

IEC Members:

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)

Member 6 (name, position, science/non-science, affiliated/non-affiliated, male/female)

Member 7 (name, position, science/non-science, affiliated/non-affiliated, male/female)

Member 8 (name, position, science/non-science, affiliated/non-affiliated, male/female)

Member 9 (name, position, science/non-science, affiliated/non-affiliated, male/female)

Member 10 (name, position, science/non-science, affiliated/non-affiliated, male/female)

Member 11 (name, position, science/non-science, affiliated/non-affiliated, male/female)

Member 12(name, position, science/non-science, affiliated/non-affiliated, male/female)

Member 13 (name, position, science/non-science, affiliated/non-affiliated, male/female)

Member 14 (name, position, science/non-science, affiliated/non-affiliated, male/female)

AGENDA

1. CALL TO ORDER
2. DETERMINATION OF QUORUM
3. DISCLOSURE OF CONFLICT OF INTEREST
4. APPROVAL OF THE AGENDA
5. APPROVAL OF THE MINUTES OF THE LAST MEETING
6. PROTOCOL REVIEW

6.1. FULL BOARD REVIEW

6.1.1. Protocols for Initial Review

Protocol Code	
Submission date	
Protocol Title	
Principal Investigator	
Reviewers	
Sponsor or CRO	
Time allotment	

6.1.2. Protocols for Modification or Resubmissions

Protocol Code	
Re-Submission date	

Protocol Title	
Principal Investigator	
Reviewers	
Sponsor or CRO	
Time allotment	

6.1.3. Amendments

Protocol Code	
Approval date	
Submission date	
Protocol Title	
Principal Investigator	
Reviewers	
Sponsor or CRO	
Time allotment	

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

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

6.1.5. SAE Reports

Protocol Code	
Approval date	
Report date	
Protocol Title	

Principal Investigator	
Reviewers	
Sponsor or CRO	
Time allotment	

6.1.6. Requests, Queries, and Complaints

Protocol Code	
Approval date	
Application date	
Protocol Title	
Principal Investigator	
Reviewers	
Sponsor or CRO	
Time allotment	

6.1.7. Site Visit Reports

Protocol Code	
Protocol Approval date	
Protocol Title	
Site Visit date	
Principal Investigator	
Reviewers	
Sponsor or CRO	
Time allotment	

6.1.8. Study Termination

Protocol Code	
Protocol Approval date	
Application date	
Protocol Title	
Principal Investigator	

Reviewers	
Sponsor or CRO	
Time allotment	

6.1.9. Continuing and Progress Reports

Protocol Code	
Protocol Approval date	
Application date	
Protocol Title	
Principal Investigator	
Reviewers	
Sponsor or CRO	
Time allotment	

6.1.10. Final Reports

Protocol Code	
Protocol Approval date	
Application date	
Protocol Title	
Principal Investigator	
Reviewers	
Sponsor or CRO	
Time allotment	

7. OTHER MATTERS:

8. ADJOURNMENT:

Kindly make it convenient to attend and bring these relevant documents for your ready reference.

Yours sincerely,

Member Secretary