KEMPEGOWDA INSTITUTE OF MEDICAL SCIENCES AND RESEARCH CENTER

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INSTITUTIONAL ETHICS COMMITTEE

(Registered under CDSCO vide File No.ECR/307/KIMS/Inst/Kar/2013)

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STANDARD OPERATING PROCEDURE (WORKING MANUAL)

Version: V3.0.1 | Date: 02-09-2015

INDEX

INTRODUCTION

1. PURPOSE

To specify the purpose of the Institutional Ethics Committee (IEC), KIMS & RC, Bangalore and state the objectives of this SOP/working manual.

2. SCOPE

Applicable to IEC, KIMS & RC, Bangalore.

3. RESPONSIBILITY

The members of the Institutional Ethics Committee (IEC), KIMS & RC, Bangalore, will implement this SOP.

4. PROCEDURE

4.1. The KIMS Institutional Ethics Committee (IEC) reviews biomedical research in the interest of safeguarding the safety, dignity, rights and well being of all research participants and the concerned community at large. The IEC will also ensure that there is regular evaluation/audit of ongoing research activities as per the protocols which are approved by the IEC, taking in to account the interests and need of the researchers, and having the regard for the requirements of relevant regulatory agencies and applicable laws.

4.2. The objective of this SOP is to contribute to the effective functioning of the IEC so that a quality and consistent ethical review mechanism for health and biomedical research is put in place for all proposals dealt by the committee as prescribed by ethical guidelines for biomedical research on human subjects of ICMR.

CONSTITUTION OF INSTITUTIONAL ETHICS COMMITTEE

1. PURPOSE

To constitute and establish the Institutional Ethics Committee (IEC), KIMS & RC, Bangalore.

2. SCOPE

Applicable to IEC, KIMS & RC, Bangalore.

3. RESPONSIBILITY

The Dean and Principal, KIMS & RC, Bangalore.

4. PROCEDURE

4.1. The Dean and Principal of Kempegowda Institute of Medical Sciences & Research Center will constitute the IEC to ensure a competent review of all ethical aspects of the research proposals received and execute the same free from any bias and influence that could affect the research objectives.

4.2. The IEC will be established in accordance with the applicable laws and regulations of the state, country and in accordance with the value and principles of the communities they serve.

4.3. The IEC will be multidisciplinary, multi-sectorial, institutional, competent and heterogeneous in composition with a balanced representation in age, gender covering the areas of science, medical, legal, social and ethical aspects.

4.4. Competent persons with adequate qualification & experience in their professional fields, proficient to review and evaluate the research proposal will be appointed be appointed as the members of the IEC.

4.5. The term of the IEC members appointed will be for a period of 3 years and the list of the IEC members and their curriculum vitae will be available for audit/inspection. The committee will be reconstituted every 03 years or as necessary if there are any vacancies; 50% of the constituent members will be replaced during the reconstitution.

4.6. The members will have full rights to withdraw from the committee by forwarding his/her resignation at any time with or without proper reasons and if the member remains non-available for consecutive 02 meetings such a member can be removed or replaced by another person from the same area of interest.

4.7. Experts / independent consultants who are non-members may be invited for an opinion on specific topics. However, they will not have the voting rights.

4.8. All members should maintain confidentiality of all discussions during the meetings. The IEC members who are independent of the investigator and the sponsor of the research proposals will be able to vote/opine on such matters. Conflict of interest should be declared by the members of the IEC.

COMPOSITION OF INSTITUTIONAL ETHICS COMMITTEE

1. PURPOSE

To appoint suitable members to the IEC, KIMS & RC.

2. SCOPE

Applicable to KIMS Bangalore.

3. RESPONSIBILITY

The Dean and Principal, KIMS Bangalore and Chairman/Member Secretary are responsible for implementing the SOP.

4. PROCEDURE

4.1. The chairman of the IEC will be from outside the institution. The member secretary and other members nominated by head of the institution can be from within or outside the institute. The committee shall include a total of 8-10 members (maximum of 15) consisting of:

1. Chairman (from outside the institution)
2. Basic medical scientists (1 to 2)
3. Clinicians (1 to 2)
4. Legal expert (an advocate or retired judge)
5. Social scientist / representative of NGO
6. Philosopher / ethicist / philanthropist
7. Lay person from the community
8. Member secretary

4.2. In case of animal experimentations, the proposal will be reviewed and approved by the KIMS institutional animal ethics committee, which is registered under CPCSEA as per norms.

RESPONSIBILITIES OF THE IEC

1. PURPOSE

To hold regular Ethics Committee meetings to review and monitor proposed research projects involving human subjects.

2. SCOPE

Applicable to all the members of the IEC, KIMS & RC, Bangalore.

5. RESPONSIBILITY

The Chairman and all members of the IEC are responsible for implementing the SOP.

3. PROCEDURE

3.1. The Institutional Ethics Committee shall ensure that the research protocols carried out at Kempegowda Institute of Medical Sciences , Bangalore are:

1. Sound in scientific design and statistical validity and are conducted, considering the essentiality of research.
2. The committee assures the research is conducted according to the parameters of ICH-GCP guidelines.
3. Shall not compromise on the dignity, safety, rights and well-being of the participants/subjects considering the risks and benefits involved.
4. IEC accepts/approves research proposals conducted by ICH-GCP trained investigators.
5. Are conducted under the supervision of clinician(s) with the required qualification, experience and expertise relevant to the area of research.
6. Should include solely the subjects/participants who themselves or through their legal representatives have given written informed content for participation in the research study according to the Modified Declaration of Helsinki, ICH-GCP and ICMR Guidelines.

APPLICATION / SUBMISSION OF RESEARCH PROPOSAL TO THE IEC

1. PURPOSE

To submit a research proposal/protocal to the IEC, KIMS & RC for review.

2. SCOPE

Applicable to IEC, KIMS & RC Bangalore.

3. RESPONSIBILITY

The Principal Investigator of the proposed clinical trial or study is responsible for implementing the SOP.

4. PROCEDURE

4.1. The applicant of the research proposal (generally the principal investigator) is required to submit his/her application in the prescribed format (which will be provided by the KIMS Research Cell after registration of the proposal in the KIMS Clinical Trial Registry).

4.2. The study protocol with relevant documents (as mentioned in the application form) duly signed by the Principal Investigator (PI) should be submitted to the IEC at least 15 days before the scheduled meeting of IEC.

4.3. For all projects sponsored/funded by external agencies, an IEC fee of Rs. 25,000/- should be paid by way of cheque/demand draft drawn in favor of “Principal, KIMS.”

4.4. All sponsored/funded projects should obtain a prior approval / permission from the “Chairman, Governing Council, KIMS.”

DOCUMENTS FOR SUBMISSION

1. PURPOSE

To check the research proposal/protocols submitted by the investigators for completeness.

2. SCOPE

Applicable to IEC, KIMS & RC, Bangalore.

3. RESPONSIBILITY

The Principal Investigator and Member Secretary/his designated staff are responsible for implementing the SOP.

4. PROCEDURE

The list of documents for submission for Institutional Ethics Committee (IEC), KIMS, Bangalore are:

1. Name of the applicant with designation.
2. Name of the Institute/ Hospital / Field area where research will be conducted.
3. Approval of the Head of the Department / Institution.
4. Protocol of the proposed research.
5. Ethical issues in the study and plans to address these issues.
6. Proposal should be submitted with all relevant enclosures like proforma, case report forms, questionnaires, follow-up cards, etc.
7. Informed consent process, including patient information sheet and informed consent form in local language(s).
8. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country / countries, if available.
9. Curriculum vitae of all the investigators with relevant publications in last five years.
10. Any regulatory clearances required.
11. Source of funding and financial requirements for the project.
12. Other financial issues including those related to insurance.
13. An agreement to report only Serious Adverse Events (SAE) to IEC.
14. Statement of conflicts of interest, if any.
15. Agreement to comply with the relevant national and applicable international guidelines.

16. A statement describing any compensation for study participation (including expenses and access to medical care, loss of wages, logistics, etc.) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.

17. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.

18. Any other information relevant to the study.

REVIEW PROCEDURE

1. PURPOSE

To review the clinical trial or study proposals submitted by the investigators both scientifically and ethically.

2. SCOPE

Applicable to IEC, KIMS & RC, Bangalore.

3. RESPONSIBILITY

The Chairman and all members of the IEC, KIMS & RC are responsible for implementing the SOP.

4. PROCEDURE

4.1. The IEC shall meet once in three months or as deemed necessary. Advance notice of 7 days before the scheduled meeting shall be sent out to the IEC members, along with the agenda.

4.2. The Chairperson will conduct all meetings of the IEC. If for reasons beyond control, the Chairperson is not available, the Deputy Chairperson or an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. The Member Secretary shall convene the IEC meetings.

4.3. The requisite quorum of minimum 5 members should be present at each review meeting. At least one of the IEC members who are not affiliated to the institute should be present during each meeting.

4.4. The Member Secretary or any other person designated by the Chairperson shall record the minutes of the meeting and circulate the same to the members within two weeks of the meeting for concurrence and approval of the same.

4.5. The study team (the principal investigator or his/her representative) may be called during the meeting to present the study or to answer/clarify specific queries; however shall not participate in the decision making/voting process of the study.

4.6. The decision will be arrived through consensus and not by vote, but when a consensus appears unlikely, voting can be performed.

4.7. The committee shall give its opinion on the proposal in one of the following ways.

1. Approved
2. Disapproved
3. Approved subject to modification(s)
4. Termination/suspension of any prior approval
5. Repeat review/resubmission

4.8. In all cases, the study shall be unambiguously identified by the title and number of the protocol. All documents reviewed will be listed in the response letter which will also state the date of the meeting and the members present at which the study was reviewed.

4.9. The Chairman/Member Secretary will convey the decision of the committee to the principal investigator in writing.

4.10. Any amendment to a study related document which is administrative in nature and does not involve change in study design or safety criteria may be provisionally approved in writing by

the Member Secretary/Monitoring Committee without calling for a full meeting. The other members will be informed of the amendment during the subsequent regular meeting of the committee.

MONITORING COMMITTEE

1. PURPOSE

To periodically scrutinize the status of the ongoing research projects and assist in expedited ethics committee review process and to clarify or address minor issues which may not require review by the full ethics committee.

2. SCOPE

Applicable to IEC, KIMS & RC, Bangalore.

3. RESPONSIBILITY

The Chairman, Member Secretary and all members of the Monitoring Committee, KIMS & RC are responsible for implementing the SOP.

4. PROCEDURE

4.1. The Monitoring Committee will be appointed by the Dean & Principal, KIMS, Bangalore, in consultation with the IEC.

4.2. The members of the Monitoring Committee will periodically scrutinize the status of the ongoing research projects which have cleared by the KIMS IEC.

4.3. The Monitoring Committee will also meet on an as-needed basis and assist the Member Secretary in expedited review of research projects.

4.4. The Member Secretary and/or Monitoring Committee will inform the full members of the IEC, KIMS, as to the decisions taken, if any, during the expedited review process.

4.5. The monitoring committee will be empowered to address minor issues and clarifications like:

a. Change in the co-investigator/s, sub-investigator/s
b. Change in contact address
c. Change in logistics
d. Minor modifications in the protocol

EXPEDITED REVIEW PROCEDURE

1. PURPOSE

To provide expedited review and approval of a research proposal.

2. SCOPE

Applicable to the members of the IEC, KIMS & RC, Bangalore.

3. RESPONSIBILITY

The Member Secretary and the members of the Monitoring Committe of the IEC, KIMS & RC, Bangalore, are responsible for implementing the SOP.

4. PROCEDURE

4.1. The IEC will receive and consider the proposals for expedited review and approval for the studies having/involving:

1. No risk to trial participants.
2. Re-examination of a proposal already examined by the IEC.
3. Study of minor nature like the examination of case records.
4. Projects of MBBS and MD/MS students (other than their dissertation protocols) if they do not include drug trial and any potential risk to study subjects.

4.2. All other proposals which do not comply with the above criteria will be reviewed in the Regular Ethics Committee meeting.

4.3. All expedited approvals will be given in a meeting of the Monitoring Committee of five members (nominated by the Member Secretary and approved by the Chairman of the IEC). The members of the monitoring committee including the Member Secretary will be present for the meeting.

4.4. Decision taken by the Sub-Committee on expedited approvals will be brought to the notice of themain committee members at next regular meeting of the IEC and their concurrence taken into record.

ELEMENTS OF REVIEW

1. **PURPOSE**
   To make a decision regarding approval of the submitted research proposal.

2. **SCOPE**
   Applicable to IEC, KIMS & RC, Bangalore.

3. **RESPONSIBILITY**
   All the members of the IEC, KIMS & RC are responsible for implementing the SOP.

4. **PROCEDURE**
   The elements in the review procedure include:

   1. Scientific design and conduct of the study.
   2. Approval of appropriate scientific review committees / regulatory bodies.
   3. Examination of predictable risks/harms.
   4. Examination of potential benefits.
   5. Procedure for selection of subjects in methodology including inclusion/exclusion, withdrawal criteria and other issues like advertisement details.
   6. Management of research related injuries, adverse events.
   7. Compensation provisions.
   8. Justification for placebo in control arm, if any.
   9. Availability of products after the study, if applicable.
   10. Patient information sheet and informed consent form in local language.
   11. Protection of privacy and confidentiality.
   12. Involvement of the community, wherever necessary.
   13. Plans for data analysis and reporting.
   14. Adherence to all regulatory requirements and applicable guidelines.
   15. Competence of investigators, research and supporting staff.
   16. Facilities and infrastructure of study sites.
   17. Criteria for withdrawal of patients, suspending or terminating the study.

COMMUNICATIONS OF THE IEC

1. PURPOSE

To communicate the decision of IEC to the applicants.

2. SCOPE

Applicable to the IEC of KIMS & RC, Bangalore.

3. **RESPONSIBILITY**

Member Secretary is responsible for implementing this SOP.

4. **PROCEDURE**

4.1. A decision of the IEC will be communicated to the applicant. A certificate of the approval will be sent to the applicant within 2 weeks of the study review. The approval will be valid only for three years or for the duration of the project whichever is less. Investigator has to get his or her project reapproved after three years if necessary.

4.2. The communication of the decision will include:

1. Name and address of IEC.
2. The date and place of decision.
3. The name and designation of the applicant.
4. Title of the research proposal reviewed
5. The clear identification of protocol no., version no., date, amendment no. date.
6. A clear statement of decision reached.
7. Any advice by the IEC to the applicant.
8. In case of conditional decision any requirement by IEC including suggestions for revision and theprocedure for having the application reviewed.
9. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.
10. Signature of the member secretary with date.

RESPONSIBILITIES OF PRINCIPAL INVESTIGATOR (PI)

1. PURPOSE

To state clearly the responsibilities of the Principal Investigator (PI).

2. SCOPE

Applicable to IEC, KIMS & RC, Bangalore.

3. RESPONSIBILITY

The Principal Investigator of the proposed clinical trial or study.

4. PROCEDURE

The responsibilities of the Principal Investigator (PI) include:

1. The principal investigator should be ICH-GCP certified regular employee of the institute (KIMS & RC, Bangalore) to conduct clinical research.
2. No subject shall be admitted to the study before the written approval of IEC.
3. To strictly maintain respect, privacy and confidentiality of the study subjects.
4. To remain compliant to research guidelines.
5. If the study period is of longer duration required to submit interim report on the status of the study if asked by the IEC.
6. The vulnerable population like the very poor, prisoners, tribals, students, women, children, elderly and psychiatrically ill should not be exploited.
7. The principal investigator/ research coordinator should be available all the time by phone to answer the queries of the study subjects, IEC and the sponsor.
8. To be kept informed of amendments/ revisions to any study as well as patient safety.
9. A report of each serious adverse event with regard in the study to the committee and the sponsor.
10. To be kept informed of study completion or discontinuation if any stating reasons.
11. To restart the discontinued study prior approval of the IEC is mandatory.
12. Report any deviation from or changes in the protocol to eliminate immediate hazards to the trial subjects.
13. Report any changes increasing the risk to subjects and/ or affecting significantly the conduct of the trial.

14. No deviations from, or change of the protocol should be initiated without prior written IEC approval of the amendment except when necessary to eliminate immediate hazards to the subjects or when the changes involve only logistical or administrative aspects of the trial (e.g. change of monitor's telephone numbers).

15. Maintain accountability and transparency.

MONITORING AND FOLLOW-UP OF RESEARCH STUDIES

1. PURPOSE

To monitor the implementation and execution of the research projects as per the approved protocol.

2. SCOPE

Applicable to the IEC, KIMS & RC, Bangalore.

3. RESPONSIBILITY

Members of IEC and the Monitoring Committee and the Principal Investigators are responsible for implementing this SOP.

4. PROCEDURE

4.1. The members of the IEC and the monitoring committee will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of research.

4.2. Progress of all the research proposals will be followed at regular interval of once a year. But in special situations, IEC or the monitoring committee will conduct the follow-up review at shorter intervals basing on the need, nature and events of research project.

4.3. All the requirements and procedures for the follow-up review will be similar to that of initial and main review.

4.4. Following instances and events will require the follow-up review:

1. Any protocol amendment likely to affect rights, safety or well being of research subject of conduct of study.
2. Serious or unexpected ADR related to study or product, action taken by Investigator, sponsor and Regulatory authority.
3. Any event/ information that may affect the benefit/risk ratio of the study.

4.5. A decision of follow up review will be issued and communicated to the applicant indicating modification / suspension / termination of the project.

4.6. In case of premature suspension/termination, the applicant must notify the IEC of the reasons forthe suspension/termination with a summary of the result.

4.7. Applicant must inform the time of completion of study and must send the result summary to the IEC. IEC must receive a copy of final summary of study completed from the applicant.

RECORDS AND ARCHIVES

1. PURPOSE

To archive the study related documents, proceedings and communications.

2. SCOPE

Applicable to IEC, KIMS & RC, Bangalore.

3. RESPONSIBILITY

The Member Secretary of the IEC, KIMS is responsible for implementing the SOP.

4. PROCEDURE

The documents which will be maintianed and archived include:

1. Curriculum Vitae (CV) of all members of IEC.
2. Copy of all study protocols with enclosed documents, progress reports, and SAEs.
3. Minutes of all meetings duly signed by the Chairperson.
4. Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.
5. Copy of all correspondence with members, researchers and other regulatory bodies.
6. Final report of the approved projects.
7. The IEC shall retain all relevant records (e.g. written procedures, members, submitted documents, minutes of meeting and correspondence) for a period of at least 5 years after completion of the trail and make them available for auditing upon request by the regulatory authority.

APPENDIX – 1: KIMS IEC REGISTRATION CERTIFICATE / LETTER

File No. ECR/307/KIMS/Inst/Kar/2013

From:

The Drugs Controller General (India)
Directorate General of Health Services

FDA Bhawan, Kotla Road,
New Delhi – 110 002
Dated: 20-4-2013

To,

The Chairman
KIMS Institutional Ethics Committee
Kemegowda Institute of Medical Sciences
Institutional Ethics Committee
Banashankari, 2nd stage, Bagalore-560070

SUB: - Ethics Committee Registration No. ECR/ 216 /Inst/Kar/2013 issued under Rule 122DD of the Drugs & Cosmetics Rules1945.

Dear Sir

Please refer to your application no.KIMS/0320/2436, dated , 15 March, 2013 Dy. No. 13605 Fts no. 19142/2013 dated 28.03.2013 submitted to this office for the Registration of Ethics Committee Based on the documents submitted by you, this office hereby registers the. **KIMS Institutional Ethics Committee**, situated at, **Kemegowda Institute of Medical Sciences Institutional Ethics CommitteeBanashankari, 2nd stage, Bagalore-560070 71/1, India Registration number** ECR/216/Inst/Kar/2013 as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to the following conditions:

1. This Registration is subject to the conditions specified under Rule 122DD and Appendix VIII of Schedule-Y of Drugs and Cosmetics Act, 1940 and Rules 1945.
2. The Ethics Committee shall review and accord its approval to a clinical trial at appropriate intervals as specified in Schedule Y and the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well being of the trial subjects.
3. In the case of any serious adverse event occurring to the clinical trial subjects during the clinical trial, the Ethics Committee shall analyze and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.
4. The Ethics Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organization to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of clinical trial.
5. The licensing authority shall be informed in writing in case of any change in the membership or the constitution of the ethics committee takes place.
6. All the records of the ethics committee shall be safely maintained after the completion or termination of the study for not less than five years from the date of completion or termination of the trial (Both in hard and soft copies).
7. If the Ethics Committee fails to comply with any of the conditions of registration, the Licensing Authority may, after giving an opportunity to show cause why such an order should not be

passed, by an order in writing stating the reasons therefore, suspend or cancel the registration of the Ethics Committee for such period as considered necessary.

8. This registration shall be in force for a period of three years from the date of issue, unless it is sooner suspended or cancelled.

9. Ethics Committee shall consist of not less than seven members and is subject to a maximum of 15. One among its members, who is from outside the institute, shall be appointed as chairman, one member as a Member Secretary and rest of the members shall be from Medical, Scientific , Non Medical and Non-scientific fields including lay public

10. The committee shall include at least one member whose primary area of interest or specialization is Non-scientific and at least one member who is impendent of the institution besides; there should be appropriate gender representation on the Ethics Committee.
11. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

12. Members should be conversant with the provisions of clinical trials under this Schedule, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

    a) For review of each protocol the quorum of Ethics Committee shall be at least five members with the following representations:

        I. Basic medical scientist (preferably one pharmacologist)

        II. Clinician

        III. Legal expert

        IV. Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person.

        V. Lay person from community

13. The members representing medical scientist and clinicians should have Post graduate qualification and adequate experience in their respective fields and aware of their role and responsibilities as committee members.
14. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.
15. There should be no conflict of interest. The members shall voluntarily withdraw from the Ethics Committee meeting while making a decision on an application which evokes a conflict of interest which may be indicated in writing to the Chairman prior to the review and be recorded so in the minutes. All members shall sign a declaration on conflict of interest.
16. Subject experts or other experts may be invited to the meetings for their advice. But no such expert shall have voting rights.
17. This certificate is issued to you on the basis of declaration/submission by you that yours is an Institution and registration is sought for Institutional Ethics Committee.

Yours Faithfully

(Dr. G.N. Singh)
Drugs Controller General (I) & Licensing Authority

APPENDIX – 2: CONSTITUTION OF THE INSTITUTIONAL ETHICS COMMITTEE - KIMS

The Institutional Ethics Committee - KIMS has been reconstituted as per ICH-GCP / ICMR guidelines w.e.f. 01-01-2015 to review and approve the various research proposals / projects by the faculty / postgraduates.

SL. NO.	NAME & ADDRESS	GENDER	SPECIALTY	AFFILIATION	ROLE OF THE IEC MEMBER
1	**Prof Smt Himalakshi** Ex-Principal, VV Puram Law College Bangalore – 560 004 Phone: 9342652902 Email: himalakshipk123@yahoo.com	Female	Legal expert	Principal (Rtd.) VV Puram College of Law, Bangalore	Chairperson (from outside the institution)
2	**Dr B V Chandregowda** 720/A-7, 3rd Main, 9th Cross, HAL II Stage, Bangalore – 560 038 Mobile: 9845006520 Fax No. 080-26712798 E-mail: dr.bvc@hotmail.co.in	Male	Medical Scientist / Clinician	Dean & Principal KIMS, Bangalore	Affiliate Member
3	**Dr I Suresh** Omkar, No. 67/1, Sri Ram Mandir Road, Basavanagudi, Bangalore – 560 004 Ph: 080-26620036 Mobile: 9845268610 E-mail: isnbps@gmail.com	Male	Medical Scientist / Clinician	Medical Superintendent and Professor of Orthopedics KIMS Bangalore	Affiliate Member
4	**Smt Poornamma** No. 4, Nele, 80 ft. Road, 3rd Phase, 6th Block BSK 3rd Stage, Bangalore – 560 085 Mobile: 9880861627 E-mail: poornabhat@gmail.com	Female	Social Scientist	Professor of Sociology (Rtd.), Social Scientist	Member (from outside the institution)
5	**Smt Kalavathy S R** No. 305 3rd Cross, 1st Block Jayanagar, Bangalore – 560 011 Mobile: 9902002654 E-mail: kashisbabu@yahoo.co.in	Female	Lay person	Social Worker	Member (from outside the institution)
6	**Dr N Srinivasa Prabhu** No. 17, Balaji Nilaya, 3rd Cross, 4th Block, Kumara Park West, Bangalore – 560 020 Mobile: 93412231404 Fax No. 080-26613255 E-mail: ncsprabhu@yahoo.co.in	Male	Medical Scientist / Clinician	Professor and Head of Emergency Medicine KIMS Bangalore	Member

SL. NO.	NAME & ADDRESS	GENDER	SPECIALTY	AFFILIATION	ROLE OF THE IEC MEMBER
7	**Dr Nirmala Shivalingaiah** K-60 (Upstairs), 11th Cross, C.N. Puram, Bangalore – 560 021 Mobile: 9448050589 Fax No.080-26613255 E-mail: drnirmalaobg@gmail.com	Female	Medical Scientist / Clinician	Professor and Head of Obstetrics and Gynecology KIMS Bangalore	Member
8	**Dr S Srinivasa** No. 79, II Main, II Cross, Ganganagar, Bangalore – 560 032 Mobile: 9341238129 Fax No.080-26613255 E-mail: drsrinivas3@yahoo.in	Male	Medical Scientist / Clinician	Professor and Head of Pediatrics KIMS Bangalore	Member
9	**Dr R Shubha** No. 67/2, Sri Ram Mandir Road, Basavanagudi, Bangalore – 560 004 Mobile: 9741898698 E-mail: shubsudarshan@gmail.com	Female	Basic Scientist	Professor and Head of Anatomy KIMS Bangalore	Member
10	**Dr D H Ashwathnarayana** No. 1785, 4th Cross, 3rd Main, Prakash Nagar, Rajajinagar, Bangalore – 560 021 Mobile: 9341948189 Fax No.080-26712798 E-mail: dhashwathnarayana@gmail.com	Male	Basic Scientist	Professor and Head of Community Medicine KIMS Bangalore	Coordinator
11	**Dr H P Pundarikaksha** No. 20, Shreyas, Devarakere Extension, Kalyan Nagar, Bangalore – 560 061 Mobile: 9880052054 E-mail: drpundarikahp@gmail.com	Male	Basic Scientist	Professor and Head of Pharmacology KIMS Bangalore	Member Secretary & Convener

APPENDIX – 3: CONSTITUTION OF THE MONITORING COMMITTEE, IEC- KIMS

SL. NO.	NAME	DESIGNATION
1	**Dr H P Pundarikaksha** Professor and HOD of Pharmacology KIMS, Bangalore	Member Secretary & Convener
2	**Dr D H Aswathnarayan** Professor and HOD of Community Medicine KIMS, Bangalore	Coordinator
3	**Dr K Girish** Professor of Pharmacology KIMS, Bangalore	Member
4	**Dr R Vijendra** Assistant Professor of Pharmacology KIMS, Bangalore	Member
5	**Dr G V Vidyasagar** Assistant Professor of Biochemistry KIMS, Bangalore	Member

APPENDIX – 4: SUPPORTING STAFF

SL. NO.	NAME	DESIGNATION
1	**Dr Gangaboraiah** Professor of Community Medicine KIMS, Bangalore	Statistical Consultant & Expert Invitee
2	**Smt Padma** KIMS Office	First Division Assistant
3	**Smt Sunandamma B** KIMS Office	Typist / stenographer
4	**Smt Umadevi L** KIMS Office	Typist / stenographer

APPENDIX – 5: PROFORMA FOR INITIAL REGISTRATION OF RESEARCH PROJECTS / STUDIES

KIMS RESEARCH CELL

REGISTRATION OF RESEARCH PROJECTS / STUDIES

DEPARTMENT:

Title of the study	
Principal investigator / s	
Study coordinator / s	
Date of study initiation	
Date of IEC clearance	
Proposed duration of study	
Expected date of study completion/ termination	
Study sponsor & protocol no.	
Cost / source of funds	

Signature of the Principal Investigator **Signature of the HOD**

Research Cell I/C (Pharmacovigilance Unit) **Academic Registrar**

Registration No.

Date

APPENDIX – 6: PROFORMA OF INITIAL REVIEW SUBMISSION FORM FOR ETHICAL CLEARANCE

FOR OFFICE USE ONLY					
Sl. No.	**Date of Submission**	**Approved / Not Approved**	**Date of Resubmission**	**Date of Approval**	**Remarks**

Sl. No.	**Title**	**Particulars**
1	Title of the Research Project	
2	Name of the Principal Investigator (PI) with Qualification and Designation	Signature
3	Name of the Co-Investigator(s) with Qualification and Designation	1. 2. 3. 4.
4	Name of the Institute / Department where research is to be conducted	
5	Name of the sponsor / funding source / financial allocation for the project	
6	Duration of the project / trial	
7	Need for the study / relevant background information	
8	Principal objectives of the study	
9	Usefulness of the project / trial	

Sl. No.	Title	Particulars
10	Expected 'benefits' to volunteers / community	
11	Any other benefits	
12	Anticipated 'risks' (adverse events, injury, discomfort, etc), if any	
13	Proposed efforts to minimize the 'risks'	
14	Proposed measures to maintain confidentiality of records / data	
15	Provision for 'wage compensation' to the research subjects / participants	
16	Patient information sheet	Enclosed / Not enclosed English / Vernacular
17	Informed Consent Process (Written / Verbal)	
18	Conflict of Interest, if any	
19	Specific ethical issues, as identified by the investigating team	
20	DCGI clearance (for clinical trials of new drugs)	Obtained / Not obtained / Not applicable
21	Insurance status of the project	Insured / Not insured

Sl. No.	Title	Particulars
22	List of documents enclosed for ethical review	1. 2. 3. 4. 5. 6.
23	Approval of the Head of the Department with signature	

APPENDIX – 7: CONSENT LETTER OF THE MEMBERS, IEC

From,

_____

_____

Date: _____

Place: _____

To,

Dean & Principal,

KIMS, Bangalore

Sub: **Consent to be a Member /Institutional Member Secretary / Chairman of Institutional Ethics Committee (Human Studies)**

Dear Sir/Madam

In response to your letter stated above, I give my consent to become a Member/Member Secretary/Chairman of IEC of KIMS, Bangalore. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues. I shall be willing for my name, profession and affiliation to be published I shall not keep any literature or study related document with me after the discussion and final review.

I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel.

I herewith enclose my C.V.

Thanking you,

Your Sincerely,

Signature: _____

Name of the Member: _____

Date:
Address:
Telephone No: Off: _____ Res: _____
Email:

APPENDIX – 8: FORMAT FOR APPROVAL OF ETHICS COMMITTEE

To,

Dr. _____

Dear Dr. _____

The Institutional Ethics Committee reviewed and discussed your application to conduct the clinical trial entitled "……." on …… [date].

The following documents were reviewed:

a. Trial protocol (including protocol amendments), dated_____ version no (s) _____.
b. Patient Information Sheet and Informed Consent Form (including updated if any) in English and/or vernacular language.
c. c. Investigator's Brochure, dated _____ version no._____.
d. Proposed methods for the patient accrual including advertisement (s) etc. proposed to be used for the purpose.
e. Principal Investigator's current CV.
f. Insurance Policy/Compensation for participation and for serious adverse events occurring during the study participation.
g. Investigator's Agreement with the Sponsor.
h. Investigator's Undertaking

The following members of the ethics committee were present at the meeting held on (date, time, place).

_____ Chairman of the Ethics Committee

_____ Member secretary of the Ethics Committee

_____ Name of each member with designation

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee to be informed about the progress of the study, any serious adverse events occurring in the course of the study, any changes in the protocol and patient information/informed consent and to provide a copy of the final report on completion.

Yours sincerely,

Member Secretary, Ethics Committee.

APPENDIX – 9: CONTENTS OF THE PROPOSED PROTOCOL FOR CONDUCTING CLINICAL TRIALS

1. Title Page

a. Full title of the clinical study.

b. Protocol/Study number, and protocol version number with date.

c. The IND name/number of the investigational drug.

d. Compete name and address of the Sponsor and contract research organization, if any.

e. List of the Investigators who are conducting the study, their respective institutional affiliations and site locations.

f. Name(s) of clinical laboratories and other departments and /or facilities participating in the study.

2. Table of Contents

a. A complete Table of Contents including a list of all Appendices.

i. Background and Introduction
   a. Preclinical experience
   b. Clinical experience
   Previous clinical work with the new drug should be reviewed here and a description of how the current protocol extends existing date should be provided. If this is an entirely new indication, how this drug was considered for this should be discussed. Relevant information regarding pharmacological, toxicological and other biological properties of the drug/biologic/medical device, and previous efficacy and safety experience should be described.

b. Study Rationale
This section should describe a brief summary of the background information relevant to the study design and protocol methodology. The reason for performing this study in the particular included by the protocol should be provided.

c. Study Objective (s) (primary as well as secondary) and their logical relations to the study design.

3. Study Design

a. Overview of the study Design: Including a description of the type study (i.e. double- blind, multicentre, placebo controlled, etc), a detail of the specific treatment groups and number of study Subject in each group and investigative site, Subject number assignment, and the type, sequence and duration of study periods.

b. Flow chart of the study.

c. A brief description of the methods and procedures to be used during the study.

d. Discussion of Study design: This discussion details the rationale for the design chosen for this study.

4. Study Population

The number of Subjects required to be enrolled in the study at the Investigative site and by all sites along with a brief description of the nature of the Subject population required is also mentioned.

5. Subject Eligibility

a. Inclusion Criteria.

b. Exclusion Criteria.

6. Study Assessments – plan procedures and methods to be described in detail.

7. Study Conduct stating the types of study activities that would be included in this section would be:

a. Medical history, type of physical examination, blood or urine testing electrocardiogram (ECG), diagnostic testing such as pulmonary function tests, symptom measurement, dispensation and retrieval of medication, Subject cohort assignment, adverse event review etc.

b. Each visit should be described separately as visit I, Visit 2, etc.

c. Discontinued Subjects: Describes the circumstances for subject withdrawal, dropouts, or other reasons for discontinuation of subjects. State how drop outs would be managed if they would be replaced.

d. Describe the method of handling of protocol waivers, if any. The person(s) who approves all such waivers should be identified and the criteria used for specific waivers should be provided.

e. Describe how protocol violations will be treated, including conditions where the study will be terminated for non-compliance with the protocol.

8. Study Treatment:

a. Dosing schedule (dose, frequency, and duration of the experimental treatment) Describe the administration of placebos and/or dummy medications if they are part of the treatment plan. If applicable, concomitant drugs(s), their doses, frequency and duration of concomitant should be stated.

b. Study drug supplies and administration: A statement about who is going to provide the study medication and that the investigational drug formulation has been manufactured following all regulations details of the product stability, storage requirement and dispensing requirement should be provided.

c. Dose modification for study drug toxicity: rules for changing the dose or stopping the study drug should be provided.

d. Possible drug interactions.

e. Concomitant therapy: the drugs that are permitted during the study and conditions under which they may be used are detailed here. Describe the drugs that a subject is not allowed to use during parts of or the entire study. If any washout period for prohibited medication are needed prior to enrolment, these should be described here.

f. Blinding procedures: A detailed description of the blinding procedure if the study employs a blind on the investigator and / or the subject.

g. Unblinding procedures: If the study is blinded, the circumstances in which unblinding may be done and the mechanism to be used for unblinding should be given.

9. Adverse Events:

a. Description of expected adverse events should be given.

b. Procedures used to evaluate an adverse event should be described.

10. Ethical Considerations: Give the Summary of:

a. Risk/benefit assessment.

b. Ethics Committee review and communications.

c. Informed consent process.

d. Statement of subject confidentially including ownership of date coding procedures.

11. Study Monitoring and Supervision:

a. A description of study monitoring policies and procedures should be provided along with the proposed frequency of site monitoring visits, and who is expected to perform monitoring.

b. Case Record (CRF) completion requirements, including who gets which copies of the forms and any specifics required in filling out the forms CRF corrections requirements, including who is authorized to make corrections on the CRF and how queries about study data are handled and how errors, if any, are to be corrected should be stated.

c. Investigator study files, including what needs to be stored following study completion should be described.

12. Investigational Product Management

a. Give Investigational product description and packaging (stating all Ingredients and the formulations of the investigational drug and any placebos used in the study).

b. The precise dosing required during the study).

c. Method of assigning treatments to subjects and the Subject identification code numbering system.

d. Storage conditions for study substances.

e. Investigational product accountability: Describe instructions for the receipt, storage, dispensation, and return of the investigational products to ensure a complete accounting of all investigational products received, dispensed, and returned /destroyed.

f. Describe policy and procedure for handling unused investigational products.

13. Data Analysis:

a. Provide details of the statistical approach to be followed including sample size, how the sample was determined, including assumptions made in making this determination, efficacy endpoints) primary as well as secondary) and safety endpoints.

b. Statistical analysis:
   i. Give complete details of how the results will be analyzed and reported along with the description of statistical tests to be used to analyze the primary and secondary endpoints defined above.
   ii. Describe the level of significance, statistical tests to be used and the methods used for missing data: method of evaluation of data for treatment failures, non-compliance, and subject withdrawals.

c. Describe statistical considerations for Pharmacokinetic (PK) analysis, if applicable

14. Undertaking by the Investigators:

15. Appendices:

Provide a study synopsis, copies of the informed consent documents (patient information sheet, informed consent form etc.; CRF and other data collection forms; a summary of relevant pre-clinical safety information and any other documents in the clinical protocol.

APPENDIX – 10: CHECKLIST FOR STUDY SUBJECT's INFORMED CONSENT DOCUMENTS

A. Essential elements:

1. Statement that the study involves research and explanation of the purpose of the research.

2. Expected duration of the Subject's participation.

3. Description of the procedures to be followed, including all procedures and description of any reasonably foreseeable risks or discomforts to the subject.

4. Description of any benefits to the subject or others reasonably expected from research. If no benefit is expected subject should be made aware of this.

5. Disclosure of specific appropriate alternative procedures or therapies available to the subject.

6. Statement describing the extent to which confidentially of records identifying the subject will be maintained and who will have access to subject's medical records.

7. Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials).

8. Compensation and/or treatment(s) available to the subject in the event of trial-related injury.

9. An explanation about whom to contact for trial related queries, rights of subjects and in the event of any injury.

10. The anticipated prorated payment, if any, to the subject for participating in the trial.

11. Subject's responsibilities on participation in the trial.

12. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.

13. Any other pertinent information.

B. Additional elements, which may be required:

1. Statement of foreseeable circumstances under which the subject's participation may be terminated by the Investigator without the subject's consent.

2. Additional costs to the subject that may result from participation in the study.

3. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by subject.

4. Statement that the subject or subject's representative will be notified in a timely manner if significant new finding develop during the course of the research which may affect the subject's willingness to continue participation will be provided.

5. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.

6. Approximate number of subjects enrolled in the study.

APPENDIX – 11: PROFORMA FOR INFORMED CONSENT FORM

INFORMED CONSENT FORM TO PARTICIPATE IN A CLINICAL TRIAL

Study Title: _____ Study Number: _____

Subject's Initials: _____ Subject's Name: _____

Date of birth/Age: _____

1. I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask question.

2. I understood that my participation in the study is voluntary and that I am free to withdraw at any time' without giving any reason, without my medical care or legal rights being affected.

3. I understand that the sponsor of the clinical trial, others working on the sponsor's behalf', the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.

4. I agree not to restrict the use of any data or result that arise from this study, provided such a use is only for scientific purpose(s).

5. I agree to take part in the above study.

Signature or Thumb impression of the subject/legally acceptable representative: _____

Signatory's Name: _____

Date _____/_____/_____

Signature of the Investigator: _____

Study Investigator's Name: _____

Signature of the Witness #1 _____ Date: _____/_____/_____

Signature of the Witness #2 _____ Date: _____/_____/_____

APPENDIX – 12: UNDERTAKING BY THE INVESTIGATOR

1. Full name, address and title of the Principal Investigator (or Investigator(s) when there is no Principal Investigator).

2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, and /or other statement(s) of qualification(s).

3. Name and address of all clinical laboratory facilities to be used in the study.

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

5. Names of the other members of the research team (Co-or sub-Investigators) who will assisting the Investigator in the conduct of the investigation (s).

6. Protocol Title and study number (if any) of the clinical trial to be conducted by the Investigator.

7. Commitments:

   i. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.

   ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the sponsor and prior review and documented approval / favorable opinion from the Ethics Committee of the amendment, expect where necessary to eliminate an immediate hazard(s) to the trial subjects or when the changes(s) involved are only logistical or administrative in nature.

   iii. I agree to personally conduct and/or supervise the clinical trial at my site.

   iv. I agree to inform all subjects, that the drugs are being used for investigational purposes and I will ensure that the requirements to obtaining informed consent and ethics committee review and approval specified in the GCP guidelines.

   v. I agree to report to the sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory and GCP guidelines.

   vi. I have read and understood the information in the Investigator' brochure, including the potential risks and side effects of the drug.

   vii. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about obligations in meeting their commitments in the trial.

viii. I agree to maintain adequate and accurate records and to make those records available for audit/inspection by the sponsor, Ethics Committee, Licensing Authority or their authorized representative, in accordance with regulatory and GCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the sponsor.

ix. I agree to promptly report to the Ethics Committee all changes in the clinical trial activities and all unanticipated problems involving risk to human subjects or others.

x. I agree to inform all unexpected serious adverse events to the sponsor as well as the Ethics Committee within seven days of their occurrence.

xi. I will maintain confidentially of the identification of all participating study patients and assure security and confidentially of study data.

xii. I agree to comply with all other requirement, guidelines and statutory obligations as applicable to clinical Investigator participating in clinical trials.

8. Signature of Investigator with date.