

K.L.E SOCIETY'S INSTITUTE OF DENTAL SCIENCES,

No. 20, Tumkur road, Yeshwanthpur Suburb,

BANGALORE -560022



Institute Ethics Committee

Standard Operating Procedures -Human Studies

**CHECKLIST FOR SUBMISSION OF APPLICATIONS FOR REGISTRATION OF
ETHICS COMMITTEE**

#	Documents required to be submitted	Status		Page No.
		Yes	No	
1.	Application for registration in accordance with the requirements as specified in Appendix VIII of Schedule Y	√		(I)
2.	Name of the Ethics Committee	√		(II)
3.	Authority under which the Ethics Committee has been constituted	√		(III)
4.	Membership requirements of the Ethics Committee	√		3
5.	The terms of reference of the committee	√		13,14
6.	Documents, if any, proving that the members of the committee are conversant with the provisions of clinical trials as per the provisions of D & C Rules and Good Clinical Practice Guidelines for clinical trials in India.	√		95-105
7.	Conditions of appointment and the quorum required.	√		3
8.	Procedure for resignation, replacement or removal of members.	√		3
9.	Address of the office of the Ethics Committee.	√		(II)
10.	Name, address, qualification, organizational title, telephone number, fax number, e-mail, mailing address and brief profile of the Chairman.	√		37-61
11.	Names, qualifications, organizational title, telephone number, fax number, e-mail and mailing address of the members of the Ethics Committee. The information shall also include member's specialty (primary, scientific or non-scientific), member's affiliation with institutions and patient group representation, if any.	√		37,62-90
12.	Details of the supporting staff.	√		38
13.	In the case of Ethics Committee existing before 08.02.2013, following should be submitted-	NA		NA
	a) Types of clinical research reviewed by the committee (e.g. pharmaceuticals, devices, epidemiological, retrospective, herbals etc.).	NA		NA
	b) Documents reviewed for every clinical trial protocol including Informed Consent documents.	NA		NA
	c) Information in respect of number of meetings of the committee and documentation of the minutes of meetings of these committees concerning clinical trials.	NA		NA
	d) Information regarding review of serious adverse events reported during the conduct of the trial.	NA		NA
14.	The standard operating procedures to be followed by the committee in general.	√		1-36
15.	Standard operating procedures to be followed by the committee for vulnerable population.	√		14
16.	Policy regarding training for new and existing committee members along with standard operating procedures.	√		13
17.	Policy to monitor or prevent the conflict of interest along with standard operating procedures.	√		14,91-94
18.	If the committee has been audited or inspected before, give details.	NA		NA
19.	Undertaking by the committee as per the format Annexed.	√		109

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Bangalore

To

The Drugs Controller General (India) & Licensing Authority
Office of the Drugs Controller General of India

SUB: Application for Registration of Institute Ethics Committee

Respected Sir/Madam,

We have prepared an application for registration of our Institute's Ethics committee in accordance with the requirements specified in Appendix VIII of Schedule Y and have included the undertaking along with the checklist of documents containing administrative and technical information. Kindly consider our application for scrutiny and the needful.

Thanking You.

Dr. Vijayalakshmi Balekundri

Chairperson, IEC

KLE Society's Institute of Dental Sciences

Bangalore-22

Date:

(1)

**Standard Operating Procedures for Institute Ethics Committee,
KLE Society's Institute of Dental Sciences, Bangalore**

NAME OF COMMITTEE: **Institute Ethics Committee, KLE Society's Institute of Dental Sciences, Bangalore**

FULL POSTAL ADDRESS: **Room No. 5, Department of Periodontics, KLE Society's Institute of Dental Sciences, #20, Yeshwanthpur Suburb, Tumkur Road, Bangalore-560022.**

I. Standard Operating Procedures (SOPs)

KIDS-B IEC SOP

Version: 1.1

Date: 31/03/2016

Pages: 110

II. SOPs prepared by:

Name and Designation	Signature with date
Dr Ashwin Prabhu Member Secretary, IEC Reader, Department of Periodontics	
Dr Sudhir R Patil Member, IEC Prof & Head, Department of Periodontics	

III. SOPs reviewed and approved by: Institute Ethics Committee

Name and designation	Signature with date
Dr Vijayalakshmi Balekundri Chairperson, IEC, KIDS, Bangalore	

IV. SOPs accepted by:

Name and designation	Signature with date
Dr Srivatsa G Principal, KIDS, Bangalore	

I. Short Description of SOP

The following may be called as “Standard Operating Procedures for the **Institutional Ethics Committee (IEC) of KLE Society’s Institute of Dental Sciences, Bangalore.**

II. Adoption of SOP

KLE Society’s Institute of Dental Sciences, Bangalore herein referred to as “KIDS-B” has adopted these written Standard Operating Procedures (SOP) to ensure the protection of the rights and welfare of human participants in biomedical, experimental and behavioral research conducted at KIDS-B.

III. Objectives of SOP

The objective of this Standard Operating Procedures of the **Institutional Ethics Committee (IEC) of KLE Society’s Institute of Dental Sciences, Bangalore** is to maintain effective functioning of the KIDS-B-IEC and to ensure quality and technical excellence and consistent ethical review of all the submitted health and biomedical research proposals and ongoing approved research studies involving human participants in accordance with the ICMR ethical guidelines for biomedical research on human subjects.

IV. Authority for constituting the KIDS-B IEC

The Principal, KIDS-B will appoint the Chairperson and all the committee members based on their competence, experience and integrity by sending an official request letter (Annexure 1A & 1B). Members will confirm their acceptance to the Principal by providing all the required information for membership (Annexure 2). The Chairperson will furnish any information or report to the Principal, KIDS-B when required.

V. Role and Responsibilities of KIDS- P IEC

The KIDS-B-IEC will review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants before approving the research proposals. The goals of research, however important, should never be permitted to override the health and well being of the human participants.

The KIDS-B-IEC will ascertain whether all the cardinal principles of research ethics viz., *Autonomy, Beneficence, Non – maleficence, Respect for Free and Informed Consent, Respect for Human Dignity, Respect for Vulnerable Persons , Respect for Privacy and Confidentiality and Justice* are taken care of in planning, conducting and reporting of the proposed research. For this purpose, it will look into the aspects of *protocol review, selection of participants, voluntary participation of potential participants, informed consent process, risk benefit ratio, distribution of burden and benefit, maintenance of privacy and confidentiality and provisions for appropriate compensations.* It will review the proposals before the commencement of the study as well as review periodically until the completion of the study through

appropriate well documented procedures. Such a review may be based on the periodic study progress reports furnished by the investigators and/or monitoring and internal audit reports furnished by the Sponsor and/or by visiting the study sites.

The mandate of the IEC shall be to review all research projects to be conducted at the Institution involving human beings directly or indirectly, irrespective of whether the research project is funded or non-funded, and if funded, then irrespective of the funding agency.

KIDS-B IEC will provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research.

In case KIDS-B IEC revokes its approval accorded to a trial protocol, it will record the reasons for doing so and at once communicate such a decision to the Investigator as well as to the Licensing Authority.

In case of serious adverse event or death occurring to the clinical trial participant, the KIDS-B IEC shall forward its report on the serious adverse event or death, after due analysis, along with its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial, to the Chairman of the Expert committee constituted by the Licensing authority under Appendix XII (gazette notification 30th January 2013) with a copy of the report to the Licensing Authority within twenty one calendar days of the occurrence of the serious adverse event or death. In case of serious adverse event, other than death occurring to the clinical trial subject, the KIDS-B IEC shall forward its report on the serious adverse event after due analysis along with its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, to the licensing authority within twenty one calendar days of the occurrence of the serious adverse event.

VI. Composition of KIDS-B-IEC

KIDS-B-IEC will be a multidisciplinary and multisectorial body in composition and independent. The number of members of the Review Board may range from 7 to 15.

The chairperson of the IEC will be from outside the Institution to maintain the independence of the Committee. The Member Secretary will belong to the same Institution and will conduct the business of the Committee. Other members will be a mix of medical / non-medical, legal, scientific and non- scientific persons and may also include members of public to reflect the different points of view.

There will be representation of age and gender in the Committee to safeguard the interest and welfare of all sections of the society. Member should be aware of local, social and cultural norms, as this is an important social control mechanism. IEC may invite subject experts to take their views, whenever it is needed.

The KIDS-B-IEC will include

1. Chairperson –from outside the institute
2. One or more persons from basic medical science area (One pharmacologist compulsorily, one female member compulsory)
3. One or more clinicians
4. One legal expert or retired judge
5. One social scientist/ representative of non-governmental voluntary organization/agency
6. One philosopher/ ethicist/ theologian
7. One lay person (non-medical background) from the community
8. Member Secretary – from within the institute

A Sub-Board of the main IEC may review proposals submitted by undergraduate or post-graduate students or if necessary, an IEC may be separately constituted for the purpose, which will review proposals in the same manner as described above.

VII. Requirements for IEC Membership

1. All members will serve for a period of 3 years on renewable basis. New members will be Included in the IEC in such a way that there will be a mix of recently included members and members with some years of experience.
2. During the term, The Principal, in consultation with the Chairman can disqualify any member if, the contribution is not adequate and/or there is long period of non-availability.
3. A member can tender resignation of his office of membership from the IEC to the Principal, through the Chairperson after serving one month advance notice.
4. The Principal of KIDS-B can replace the member of IEC as and when required.
5. Each member is required to sign the declaration and confidentiality agreement regarding IEC activities (Annexure 2)
6. Conflict of interest should be declared by members of the KIDS-B-IEC prior to review meeting.

VIII. Quorum requirements

Minimum of 50% of committee strength and not less than 6 members are required to constitute the quorum for the meeting of which at least one member has to be from outside the institution, and one member will be a non-scientific member & one from opposite gender. All decisions will be taken in meetings and not by circulation of project proposals. Quorum will have 6 members with following representations:

- (a) Basic medical scientists (preferably one pharmacologist).
- (b) Clinician
- (c) Legal expert
- (d) Social scientist / representative of non-governmental voluntary agency / philosopher / ethicist / theologian or a similar person
- (e) Lay person from the community.

IX. Conduct of KIDS- B IEC meetings

The Chairperson will conduct all meetings of the KIDS-B IEC. In the absence of the Chairperson an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/She will prepare the minutes of the meetings and get it approved by the Chairperson and all the members.

X. Independent consultants

The KIDS-B IEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups e.g. cancer patients, HIV/AIDS positive persons or ethnic minorities. They will be required to give their specialized views but should not take part in the decision making process which will be made by the members of the KIDS-B IEC.

XI. Application procedures

1. All proposals should be submitted on any working day 2 weeks in advance of scheduled meeting in the prescribed application form, the details of which are given under “XII Documentation”. The applicant may ask for copy of SOP from the IEC, if the same has not been circulated earlier or not available on the website.
2. All relevant documents should be enclosed with application form. (Documents will be available with Member - Secretary, KIDS-B IEC and Institutional Website www.kledentalbengaluru.com).
3. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators / Research Scholars shall be guided to the Chairperson KIDS-B IEC, through member secretary. In his absence via any person nominated by Chairperson, receipt of the application will be acknowledged by the IEC office.
4. Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of IEC meeting will be intimated to the PI to attend the meeting and to make a brief presentation of the proposal and to clarify the points raised by the members.
5. The decision of the committee on the proposal will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

6. All research proposals/clinical trials funded/sponsored by Pharmaceutical companies, Agencies, Multinationals etc. will be charged an administrative fee/ processing fee of 5%. Waiver of these fees is permissible for non-funded studies, departmental studies, and studies funded by organizations like ICMR, UGC, DST Government of India, State Science & Technology Department, UNICEF, WHO, USAID, Non Profitable Organizations etc.

XII. Documentation

All Research proposals (6 copies along with 1 CD/DVD) shall be submitted along with the information and documents as specified in Annexure-3A, 3B and Annexure 5-7,9&10.

XIII. Review procedures

1. The meeting of the IEC will be held on periodic intervals, i.e. 1st Monday of Jan, March, May, July, Sep, Nov, unless otherwise specified by the member secretary. Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the work load.
2. The proposals should be sent to the IEC at least 2 weeks in advance of scheduled meeting.
3. The IEC's member-secretary or secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, *exemption from review*, *expedited review* and *full review* (as described below).[Annexure 9]
4. Decisions will be taken by consensus after discussion, and whenever needed voting will be done. Decision of chairperson will be final.
5. Researchers will be invited to offer clarifications if need be. The PI / Research Scholar will then present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the Co-PI will present the proposal.
6. Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed.
7. The decisions will be minuted and Chairperson's approval taken in writing.

1. Exemption from review

Proposals which present *less than minimal risk* fall under this category as may be seen in following situations:

- Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. **Exceptions:**
 1. When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.
 2. When interviews involve direct approach or access to private papers.

2. Expedited Review

The proposals presenting *no more than minimal risk* to research participants may be subjected to expedited review. The Member- Secretary and the Chairperson of the IEC or designated member of the Committee or Subcommittee of the IEC may do expedited review only if the protocols involve -

1. Minor deviations from originally approved research during the period of approval.
2. Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
3. Research activities that involve only procedures listed in one or more of the following categories:
 - Clinical studies of drugs and medical devices only when -
 1. Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or
 2. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.
4. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.
5. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and **the same participants should not be included** in the clinical trial that may be initiated later based on the findings of the pilot study.
 - a. Research on interventions in emergency situation

When proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND) / devices / vaccine to provide emergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients -

 - i. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should

- be given to the relative/ legal guardian when available later;
- ii. When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCGI;
- iii. Only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.
- iv. If Data Safety Monitoring Board (DSMB) is constituted to review the data;

b. Research on disaster management

A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or state(s). It may be periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

- i. Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations.
- ii. Disaster-affected community participation before and during the research is essential and its representative or advocate must be identified.
- iii. Extra care must be taken to protect the privacy and confidentiality of participants and communities.
- iv. Protection must be ensured so that only minimal additional risk is imposed.
- v. The research undertaken should provide direct or indirect benefits to the participants, the disaster-affected community or future disaster- affected population and a priori agreement should be reached on this, whenever possible, between the community and the researcher.
- vi. All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.
- vii. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

6. Expedited review may also be taken up for nationally relevant proposals requiring urgent review.

3. Full Review

All research presenting with *more than minimal risk*, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable population and special groups shall be subjected to full review by all the members.

While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

- a. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture:
 - i. From healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8 week period and frequency of collection is not more than 2 times per week;

- ii. From other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg, whichever is lesser is drawn in an 8 week period and not more than 2 times per week.
- iii. From neonates depending on the hemodynamics, body weight of the baby and other purposes not more than 10% of blood is drawn within 48 – 72 hours. If more than this amount is to be drawn it becomes a risky condition requiring infusion/blood transfusion;
- iv. Prospective collection of biological specimens for research purposes by noninvasive means. For instance:
 - 1. Skin appendages like hair and nail clippings in a non-disfiguring manner;
 - 2. Dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth;
 - 3. Excreta and external secretions (including sweat);
 - 4. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue;
 - 5. Placenta removed at delivery;
 - 6. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
 - 7. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
 - 8. Sputum collected after saline mist nebulization and bronchial lavages.
- b. Collection of data through noninvasive procedures routinely employed in clinical practice. Where medical devices are employed, they must be cleared/ approved for marketing, for instance
 - i. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy;
 - ii. Weighing or testing sensory acuity;
 - iii. Magnetic resonance imaging;
 - iv. Electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow,
 - v. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- c. Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.
- d. Collection of data from voice, video, digital, or image recordings made for research purposes.
- e. Research on individual or group characteristics or behavior not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

XIV. Aspects considered during review of research proposal

1. Scientific design and conduct of the study.
2. Approval by appropriate scientific review committees / Research committee, if any.
3. Examination of predictable risks/harms
4. Examination of potential benefits.
5. Procedure for selection of subjects 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, benefits to subjects after the study is completed if applicable.
10. Patient information sheet, informed consent form in English and in local languages.
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, suspension or premature termination of a study in KIDS-B.

XV. Decision-making

1. Members will discuss the various issues before arriving at a consensus decision. When consensus is not arrived at, the decision will be made by voting procedure.
2. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
3. Decision will be made only in meetings where quorum is complete.
4. Only the members can make the decisions. The expert consultants will only offer their opinions.
5. Decision may be to approve, reject or revise the proposals. Specific *suggestions for modifications and reasons for modifications and reasons for rejection* will be given.[Annexure 9]
6. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified.
7. *Modified proposals will be reviewed by an expedited review* through identified members.
8. Procedures for appeal by the researchers will be clearly defined.

XVI. Communicating the decision

1. Decision of the meeting on the proposals will be communicated by the Member Secretary/secretariat in writing to the PI / Research Scholar within two weeks after the meeting at which the decision was

taken in the specified format. All the approvals will be valid for one year or for the duration of the project whichever is less. Investigator has to get his or her project re- approved after one year, where required.

2. The communication of the decision will include:[Annexure 10]
 - a. Name and address of IEC.
 - b. The date, place and time of decision.
 - c. The name and designation of the applicant.
 - d. Title of the research proposal reviewed.
 - e. The clear identification of protocol no., version no., date, amendment no., date.
 - f. Along with protocol, other documents reviewed- Clear description of these documents along with Version No. and Date.
 - g. List of EC members who attended the meeting- clear description of their role, affiliation and gender.
 - h. A clear statement of decision reached.
 - i. Any advice by the IEC to the applicant including the schedule / plan of ongoing review by the KIDS IEC
 - j. In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed.
 - k. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.
 - l. Signature of the member secretary with date.

XVII. Following up procedures for approved proposals by PI / Sponsor

1. IEC 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 the research.
2. Progress of all the research proposals will be followed at a regular interval of at least once a year. But in special situations, IEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.
3. Periodic status report of study should be submitted at prescribed intervals for review, along with information and documents as specified in Annexure-4A, 4B 4C & 7 based on the safety concerns and this prescribed interval should be specified in the Letter of Communication of Decision to the PI from the IEC.
4. Final report should be submitted at the end of study.
5. Following instances and events will require the follow-up review/ Renewed Approval:
 - a. Any protocol amendment likely to affect rights, safety or well-being of research subject of conduct of study.
 - b. Serious or unexpected ADR related to study or product, action taken by Investigator, Sponsor and Regulatory Authority.
 - c. Any event or information that may affect the benefit/risk ratio of the study.
6. Protocol deviation, if any, should be informed with adequate justifications.
7. Any new information related to the study should be communicated.

8. Premature termination of study shall be notified with reasons along with summary of the data obtained so far.
9. Change of investigators/sites must be informed to the office of IEC.
10. Monitoring: Oversight mechanism will be in place to monitor the approved studies. Actual site visits can be made especially in the event of reporting of adverse events or violations of human rights and appropriate action will be taken when required and communicated to the applicant indicating modification/suspension/termination /continuation of the project. In case the IEC desires so, reports of monitoring done by the sponsor and the recommendations of the DSMB may also be sought.
11. Applicant must inform the time of completion of study and must send the result summary to IEC. IEC must receive a copy of final summary of study completed from the applicant.

XVIII. Responsibilities of Sponsor/Investigator

Responsibilities of Sponsor

- (i) The clinical trial Sponsor is responsible for implementing and maintaining quality assurance systems to ensure that the clinical trial is conducted and data generated, documented and reported in compliance with the protocol and Good Clinical Practice (GCP) Guidelines issued by the Central Drugs Standard Control Organization, Directorate General of Health Services, Government of India as well as with all applicable statutory provisions. Standard operating procedures should be documented to ensure compliance with GCP and applicable regulations.
- (ii) Sponsors are required to submit a status report on the clinical trial to the Licensing Authority at the prescribed periodicity.
- (iii) In case of studies prematurely discontinued for any reason including lack of commercial interest in pursuing the new drug application, a summary report should be submitted within 3 months. The summary report should provide a brief description of the study, the number of patients exposed to the drug, dose and duration of exposure, details of adverse drug reactions (Annexure 8), if any, and the reason for discontinuation of the study or non-pursuit of the new drug application;
- (iv) Any report of serious adverse event of death occurring in clinical trial, after due analysis shall be forwarded by the sponsor to chairman of the ethics committee and chairman of the expert committee constituted by the licensing authority as defined under rule 21(b) under appendix XII of gazette notification dated 30th January 2013 with a copy of the report to the Licensing authority and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of serious adverse event of death. The report of the serious adverse event other than death, after due analysis, shall be forwarded by the sponsor to the Licensing authority, Chairman of the Ethics Committee and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event. (See Annexure 8).
- (v) In case of injury or death occurring to the clinical trial subject, the sponsor (whether a pharmaceutical company or an Institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall make payment for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the

manner as prescribed in Appendix XII of gazette notification dated 30th January 2013.

- (vi) The sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall submit details of compensation provided or paid for clinical trial related injury or death, to the Licensing Authority within thirty days of the receipt of the order of the Licensing Authority.

Responsibilities of the Investigator(s)

- (i) The Investigator(s) shall be responsible for the conduct of the trial according to the protocol and the GCP Guidelines and also for compliance as per the undertaking given in Appendix VII of schedule Y. Standard operating procedures are required to be documented by the investigators for the tasks performed by them. During and following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events. Investigator(s) shall report all serious and unexpected adverse events to the Licensing Authority defined under clause (B) of rule 21 (Schedule Y and Gazette notification 30th January 2013), the sponsor or his representative, whosoever had obtained permission from the licensing authority for conduct of the clinical trial, and the ethics committee that accorded approval to the study protocol, within twenty four hours of their occurrence. The report of the serious adverse event of death, after due analysis shall be forwarded by the investigator to Chairman of the ethics committee and Chairman of the Expert Committee constituted by the Licensing authority under Appendix XII with a copy of the report to the Licensing Authority and the head of the institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event of death. The report of the serious adverse event other than death, after due analysis shall be forwarded to the Licensing Authority, Chairman of the Ethics Committee and the Head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event.
- (ii) The investigator shall provide information to the clinical trial subject through informed consent process as provided in Appendix V of Schedule Y about the essential elements of the clinical trial and the subject's right to claim compensation in case of trial related injury or death. He shall also inform the subject or His/ Her nominee(s) of their rights to contact the sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial for the purpose of making claims in the case of trial related injury or death.

XIX. Record keeping and archiving at the office of KIDS IEC

1. All the documents and communications of IEC will be dated, filed and archived in a secure place.
2. Only the member secretary or persons, who are authorized by the Chairman of IEC will have the access to the various documents.
3. All the documents related to research proposals will be archived for a minimum period of 5 years in the Institute, following the completion /termination of the study.
4. No document (except agenda) will be retained by any IEC member.
5. At the end of each meeting, every member must return the CD/DVD containing all the research

proposals and documents to IEC office staff. They will archive one copy in IEC office and other copies will be destroyed after one year.

6. Following documents will be filed and archived with proper label on the top of file for easy identification
 - a. Constitution and composition of KIDS-B IEC
 - b. Curriculum Vitae (CV) of all members of KIDS-B IEC with records of training in Human ethics if any.
 - c. Standard Operating Procedures of KIDS-B IEC.
 - d. Annual reports
 - e. A record of all income and expenses of the EC, including allowances and reimbursements made to the secretariat and EC members;
 - f. The published guidelines for submission established by the EC.
 - g. Copy of all study protocols with enclosed documents, progress reports, and SAEs.
 - h. Agendas and Minutes of all IEC meetings duly signed by the Chairperson / Member secretary.
 - i. Copy of all existing relevant national and international guidelines on ethics and laws along with amendments.
 - j. Copy of all correspondence with members, Principal Investigators and other regulatory bodies.
 - k. Record of all notification issued for premature termination of a study with a summary of the reasons;
 - l. Final report of the approved projects, including microfilms, CDs and Video recordings.

XX. Updating KIDS-B IEC members

1. All relevant new guidelines should be brought to the attention of the members.
2. The IEC members should be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body/ bodies, so that they become aware of their role and responsibilities. For drug trial review it is preferable to train the IEC members in Good Clinical Practice. Any change in the regulatory requirements should be brought to their attention and they should be aware of local, social and cultural norms, as this is the most important social control mechanism. This is needed for maintaining quality in ethical review

XXI. Terms of reference

Terms of reference will be maintained in the office of KIDS-B IEC. This includes

- A. Membership Requirements
- B. Terms of Appointment with reference to the duration of the term,
- C. The policy for removal, replacement, resignation procedure,

D. Frequency of meetings, and

E. Payment of processing fee to the IEC for review, honorarium/ consultancy to the members/ invited experts *etc.*

The SOPs will be updated periodically based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage of members could be changed on regular basis. Preferably, IEC would appoint persons trained in bioethics or persons conversant with ethical guidelines and laws of the country. Substitute member may be nominated if meetings have been continuously missed by a member due to illness or other unforeseen circumstances.

XXII. Administration and Management

A full time secretariat and space for keeping records is required for a well-functioning IEC. The members could be given a reasonable compensation for the time spared for reviewing the proposals. Reasonable fees can be charged to cover the expenses related to review and administrative processes for any third party (protocols submitted by researchers not employed by KIDS-B) submission as described in section XI Point No 6. There should be provision for allocating reasonable amount of funds for smooth functioning of the IEC.

XXIII. Special Considerations / Protection of Vulnerable Population

While all the above requirements are applicable to biomedical research as a whole irrespective of the specialty of research, there are certain specific concerns pertaining to specialized areas of research which require additional safe guards / protection and specific considerations for the IEC to take note of. Examples of such instances are research involving children, pregnant and lactating women, vulnerable participants and those with diminished autonomy besides issues pertaining to commercialization of research and international collaboration. The observations and suggestions of IEC will be given in writing in unambiguous terms in such instances. ICMR guidelines as applicable will be followed for protection of vulnerable population.

XXIV. Policy on Conflict of Interest & Confidentiality

1. Conflict of interest will be avoided when making appointments, but where unavoidable, there will be transparency with regard to such interests.
2. Designated members of the IEC who wish to attend IEC meetings as observers should read, understand, accept and sign the confidentiality document in the Confidentiality/ Conflict of Interest Form (Annexure-12) at the beginning of the IEC meeting and/or before ethical review tasks of the IEC commence.
3. An investigator can be a member of the IEC; however, the investigator-as-member cannot participate in the review and approval process for any project in which the member is PI, Co- PI or has any other potential conflict of interest. All investigators (PI, CO-PI etc.) must declare any potential conflict of Interest while submitting research proposal (Annexure 12)
4. Any committee member with a conflicting interest in a proposal will abstain from deliberations and in decision making process on that proposal, except to provide information as requested by the committee. Such abstentions will be recorded in the minutes.

Letter Ref. No:

Date:

From

Principal,
KIDS
Bangalore

To

Sub: Constitution of Institute Ethics Committee (Human studies) - Reg.

Dear Sir / Madam,

On behalf of KLE Society's Institute of Dental Sciences, Bangalore, I request your concurrence for possible appointment as a member of Institute Ethics Committee of KIDS, Bangalore. Kindly send your written acceptance in the enclosed format and provide short curriculum vitae along with the acceptance letter.

On receipt of your acceptance, I shall send you the formal appointment letter.

Yours sincerely,

Signature:

Name:

APPOINTMENT ORDER

Dr/ Mr. / Mrs.: _____ Date: _____

I am pleased to appoint you as _____ of the Institutional Ethics Committee (IEC) (Human research) at KLE Society's Institute of Dental Sciences, Bangalore (KIDS-B) w.e.f. _____ for a term of _____ year / months provided following conditions of appointment are met.

1. You should be willing to publicize your full name, profession & affiliation.
2. You are willing to record all reimbursement for work & expenses, if any, within or related to an EC & make it available to the public upon request.
3. You consent to sign confidentiality agreement between you & the IEC regarding meeting deliberations, applications, information on research participants, & related matters.

The renewal of your appointment will be by consensus & 1 month notice on either side will be necessary prior to resignation/ termination of appointment. Terms & Conditions regarding the resignation procedure, disqualification procedures, replacement procedures etc. may be found in the Standard Operating Procedures (SOPs) of IEC, KIDS-B.

You will be paid a sum of Rs 2000/- per sitting as Honorarium for your services rendered & as per the guidelines given in Terms of Reference-IEC, KIDS-B.

We sincerely hope your association with IEC, KIDS will be fruitful to the Institute & the Community we serve.

Chairperson
(Name/Seal)
IEC, KIDS,
Bangalore –
560022

Signature of Appointee
(Name & Date)

From,

To
The Principal
KIDS
Bangalore-560022

Sub: Consent to be a member of Institute Ethics Committee (Human Studies) - Reg.
Ref: Your Letter No: dated:

Dear Sir,

In response to your letter stated above, I give my consent to become a member of IEC of KIDS 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 CV.

Thanking you,

Yours sincerely,

Signature _____

Name of the Member _____ Date:

Address:

Telephone No: (Off) (Res) email:

KLE Society's Institute of Dental Sciences, Bangalore

Institutional ethics committee

Initial Review Submission Form for Research Proposal

1. Title of the research proposal
2. Name of the Principal Investigator with qualification and designation
3. Name of the Co-Investigator(s) with qualifications and designation
4. Name of the Institute / Hospital / Field area where research will be conducted
5. Forwarding letter from the Head of the Department / Guide in case of thesis proposals.
6. Protocol of the proposed research: (includes and not limited to) clear research objectives, rationale for undertaking the investigations in human participants in the light of existing knowledge, inclusion and exclusion criteria for entry of participants, precise description of methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded etc.), intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures if any, plan to withdraw or withhold standard therapies in the course of research, plan for statistical analysis of the study, ethical issues in the study and plans to address these issues.
7. Proposal should be submitted with relevant enclosures like proforma, case report forms, questionnaires, follow-up cards, participant recruitment procedures and brochures, if any. Informed consent process, including patient information sheet and informed consent form in English and local language(s) are mandatory. Investigator's brochure for trial on drugs/ devices/ vaccines/ herbal remedies and statement of relevant regulatory clearances should be attached. Source of funding and financial requirements for the project has to be detailed.
8. For any drug / device trial, relevant pre-clinical animal data and clinical trial data from other centers within the country / other countries, if available.
9. Usefulness of the project / trial
10. Expected 'benefits' to volunteers / community. 'Benefits' to other categories if any
11. Explain all anticipated 'risks' (adverse events, injury, discomfort) of the project. Efforts taken to minimize the 'risks'. For trials, proposed compensation and reimbursement of incidental expenses and management of research related and unrelated injury/ illness during and after research period. Description of the arrangements for indemnity, if applicable in study-related injuries and description of the arrangements for insurance coverage for research participants, if applicable.

12. Agreement to report all Serious Adverse Events (SAE) to KIDS-B -IEC.
13. Other financial issues including those related to insurance.
14. An account of storage and maintenance of all data collected during the trial.
15. For international collaborative study details about foreign collaborators and documents for review of Health Ministry's Screening Committee(HMSC) or appropriate Committees under other agencies/ authority like Drug Controller General of India (DCGI)
16. For exchange of biological material in international collaborative study a MoU/ Material Transfer Agreement between the collaborating partners.
17. Statement of conflicts of interest, if any.
18. Agreement to comply with the relevant national and applicable international guidelines, Good Clinical Practices (GCP) protocols for clinical trials.
19. 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
20. A statement on, probable ethical issues and steps taken to tackle the same like justification for washout of standard drug, or the use of placebo control.
21. Curriculum vitae of all the investigators with relevant publications in last five years.
22. Plans for publication of results / positive or negative / while maintaining the privacy and confidentiality of the study participants.
23. Any other information relevant to the study.
24. Signature of the Principal Investigator with date.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal

**FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN
HUMAN SUBJECTS FOR CLEARANCE BY ETHICS COMMITTEE OF KIDS,
BANGALORE**

Submit six (6) hard copies of the Research Proposal along with Covering letter, a CD/DVD of the proposal and a 'soft copy' along with the following information to the Member Secretary, Institution Ethics Committee at the IEC office, KIDS-B.

No research project shall be / can be started unless ethics clearance/approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor vetted by the Institution Ethics Committee.

All submissions should be made in the prescribed Format of the IEC with signatures of all the investigators. The submission must be accompanied with *Participant Informed Consent Form* (PICF) and *Participant Information Sheet* (PIS), both in English and Hindi/Concerned local Language, **in a simple layman's language, in a narrative form, directed to Participant/LAR, covering all the points given**, before it can be considered for placing before the IEC. Also ensure that all the pages are numbered.

Project Submission Time: Submissions will be received on all working days. Proposals received till 15th of preceding month will be processed in the coming Institution Ethics Committee meeting and those received after 15th will be processed in the next Institution Ethics Committee meeting. All meetings of Institution Ethics Committee will be held as far as possible on first Monday of Jan, March, May, July, September, and November. The frequency will change depending upon the number of proposals and will be updated on the website: www.kledentalbengaluru.com

While submitting replies to queries raised by the IEC, the candidates are advised to mention the IEC reference number/s and also attach a copy of the comments of the IEC. Moreover if the approval is required in a particular format, the same may be submitted in a CD/DVD.

Amendment Submission: While submitting amendments in protocols a covering letter should be provided clearly stating the changes and a certificate by the PI that the changes made in the protocol will not hamper the safety of the subject in anyway.

**Form to be filled by the Principal Investigator (PI) for
submission to Institutional Ethics Committee (IEC),
KIDS-B**

(For attachment to each copy of the proposal)

Serial No of IEC
Management Office:

Proposal Title:

	Name, Designation, Department & Qualifications	Address Tel & Fax Nos. Email ID	No of projects already with Investigator	Signature
PI				
Co-PI / Collaborators				
1.				
2.				
3.				
4.				
5.				
6.				
Please attach detailed Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years).				

Tick appropriately

Sponsor Information :			
1. Indian	a) Government	<input type="checkbox"/>	Central <input type="checkbox"/> State <input type="checkbox"/> Institutional <input type="checkbox"/>
	b) Private	<input type="checkbox"/>	
2. International	Government	<input type="checkbox"/>	Private <input type="checkbox"/> UN agencies <input type="checkbox"/>
3. Industry	National	<input type="checkbox"/>	Multinational <input type="checkbox"/>
Contact Address of Sponsor:			
Total Budget :			

1.Type of Study :		
Epidemiological	<input type="checkbox"/>	Basic Sciences <input type="checkbox"/> Animal studies <input type="checkbox"/>
Clinical: Single center	<input type="checkbox"/>	Multicentric <input type="checkbox"/> Behavioral <input type="checkbox"/>
2. Status of Review:		
New	<input type="checkbox"/>	Revised <input type="checkbox"/>
3. Clinical Trials:		
Drug /Vaccines/Device/Herbal Remedies :		
i. Does the study involve use of :		
Drug	<input type="checkbox"/>	Devices <input type="checkbox"/> Vaccines <input type="checkbox"/>
Indian Systems of Medicine/ Alternate System of Medicine		Any other <input type="checkbox"/> NA <input type="checkbox"/>
ii. Is it approved and marketed		
In India	<input type="checkbox"/>	UK & Europe <input type="checkbox"/> USA <input type="checkbox"/>
Other countries, specify		
iii. Does it involve a change in use, dosage, route of administration?	Yes	No
If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained?	Yes	No
If yes, Date of permission :		
iv. Is it an Investigational New Drug?	Yes	No
If yes, IND No:		
a). Investigator's Brochure submitted	Yes	No
b). <i>In vitro</i> studies data	Yes	No
c). Preclinical Studies done	Yes	No
d). Clinical Study is : Phase I	<input type="checkbox"/>	Phase II <input type="checkbox"/> Phase III <input type="checkbox"/> Phase IV <input type="checkbox"/>

e). Are you aware if this study/similar study is being done elsewhere ? If Yes, attach details	Yes	No
4. Brief description of the proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words):		
5. Subject selection:		
i. Number of Subjects :		
ii. Duration of study :		
iii. Will subjects from both sexes be recruited	Yes	No
iv. Inclusion / exclusion criteria given	Yes	No
v. Type of subjects	Volunteers <input type="checkbox"/>	Patients <input type="checkbox"/>
vi. Vulnerable subjects (Tick the appropriate boxes)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
pregnant women <input type="checkbox"/>	children <input type="checkbox"/>	elderly <input type="checkbox"/>
fetus <input type="checkbox"/>	illiterate <input type="checkbox"/>	handicapped <input type="checkbox"/>
terminally ill <input type="checkbox"/>	seriously ill <input type="checkbox"/>	mentally challenged <input type="checkbox"/>
economically & socially backward <input type="checkbox"/>	any other <input type="checkbox"/>	
vii. Special group subjects (Tick the appropriate boxes)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
captives <input type="checkbox"/>	institutionalized <input type="checkbox"/>	employees <input type="checkbox"/>
students <input type="checkbox"/>	nurses/dependent <input type="checkbox"/>	armed <input type="checkbox"/>
any other <input type="checkbox"/>	staff <input type="checkbox"/>	forces <input type="checkbox"/>
6. Privacy and confidentiality		
i. Study involves -	Direct Identifiers <input type="checkbox"/>	
	Indirect Identifiers/coded <input type="checkbox"/>	
	Completely anonymised/ delinked <input type="checkbox"/>	
ii. Confidential handling of data by staff	Yes	No
7. Use of biological/ hazardous materials		
i. Use of fetal tissue or abortus	Yes	No
ii. Use of organs or body fluids	Yes	No
iii. Use of recombinant/gene therapy	Yes	No
If yes, has Department of Biotechnology (DBT) approval for rDNA products been obtained?	Yes	No
iv. Use of pre-existing/stored/left over samples	Yes	No
v. Collection for banking/future research	Yes	No

vi.	Use of ionising radiation/radioisotopes	Yes	No
	If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes	No
vii.	Use of Infectious/biohazardous specimens	Yes	No
viii.	Proper disposal of material	Yes	No
ix.	Will any sample collected from the patients be sent abroad ?	Yes	No
If Yes, justify with details of collaborators			
	a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	Yes	No
b) Sample will be sent abroad because (Tick appropriate box):			
<p style="text-align: center;"> Facility not available in India <input type="checkbox"/> Facility in India inaccessible <input type="checkbox"/> Facility available but not being accessed. <input type="checkbox"/> If so, reasons... </p>			
8. Consent : *Written <input type="checkbox"/> Oral <input type="checkbox"/> Audio-visual <input type="checkbox"/>			
i. Consent form : (tick the included elements)			
Understandable language <input type="checkbox"/> Alternatives to participation <input type="checkbox"/> Statement that study involves research <input type="checkbox"/> Confidentiality of records <input type="checkbox"/> Sponsor of study <input type="checkbox"/> Contact information <input type="checkbox"/> Purpose and procedures <input type="checkbox"/> Statement that consent is voluntary <input type="checkbox"/> Risks & Discomforts <input type="checkbox"/> Right to withdraw <input type="checkbox"/> Benefits <input type="checkbox"/> Consent for future use of biological material <input type="checkbox"/> Compensation for participation <input type="checkbox"/> Benefits if any on future commercialization <input type="checkbox"/> Compensation for study related injury <input type="checkbox"/> eg. genetic basis for drug development			
*If written consent is not obtained, give reasons:			
ii. Who will obtain consent ? PI/Co-PI <input type="checkbox"/> Nurse/Counsellor <input type="checkbox"/> Research staff <input type="checkbox"/> Any other <input type="checkbox"/>			
9. Will any advertising be done for recruitment of Subjects ? (posters, flyers, brochure, websites – if so kindly attach a copy)		Yes	No
10. Risks & Benefits:			
i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?		Yes	No
ii. Is there physical / social / psychological risk / discomfort?		Yes	No
If Yes, Minimal or no risk <input type="checkbox"/> More than minimum risk <input type="checkbox"/> High risk <input type="checkbox"/>			

iii. Is there a benefit a) to the subject ? Direct <input type="checkbox"/> Indirect <input type="checkbox"/> b) Benefit to society <input type="checkbox"/>		
11. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No
ii. Is there a plan for reporting of adverse events ? If Yes, reporting is done to : Sponsor <input type="checkbox"/> Ethics Committee <input type="checkbox"/> DSMB <input type="checkbox"/>	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No
vi. Are there plans for storage and maintenance of all trial database? If Yes, for how long ?	Yes	No
12. Is there compensation for participation? If Yes, Monetary <input type="checkbox"/> In kind <input type="checkbox"/> Specify amount and type:	Yes	No
13. Is there compensation for injury? If Yes, by Sponsor <input type="checkbox"/> by Investigator <input type="checkbox"/> by insurance <input type="checkbox"/> by any other <input type="checkbox"/> company	Yes	No
14. Do you have conflict of interest? (financial/nonfinancial) If Yes, specify :	Yes	No
Conflict of interest for any other investigator(s) (if yes, please explain in brief)	1 _____ Yes No 2 _____ Yes No	
15. Participant Information Sheet <i>(mark √ if yes)</i>	Attached English version Attached Hindi version	
16. Participant Informed Consent Form <i>(mark √ if yes)</i>	Attached English version Attached Hindi version	
17. Whether any work on this project has started or not?	<i>(mark √ if yes, X if no) (Please enclose a separate certificate to this)</i>	
18. In case of clinical trials CTRI status		

Checklist for attached documents:

- Covering letter, through proper channel
- Project proposal – 06 Copies
- Curriculum Vitae of Investigators
- Brief description of proposal
- Patient information sheet
- Informed Consent form
- Investigator’s brochure
- Copy of advertisements/Information brochures
- Copy of clinical trial protocol and/or questionnaire
- HMSC/DCGI/DBT/BARC clearance if required
- Undertaking that the study shall be done in accordance with ICMR and GCP guidelines
- In case of multi-centric study, IEC clearance of other centres must be provided
- Definite undertaking as to who will bear the expenditure of injury related to the project
- If an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines)
- Permission to use copyrighted Questionnaire/proforma
- Investigator should provide undertaking what they will do with the leftover sample tissue
- Certificate/undertaking as mentioned in column 17
- Others

Place:

Signature & Designation of PI/Co-PI/Collaborator

Date:

KLE Society's Institute of Dental Sciences, Bangalore
Institutional Ethics Committee

Ongoing Approved Research Review Submission Form

1. Reference number
2. Month / Year of approval
3. Number of ongoing review
4. Title of the research proposal
5. Name of the Principal Investigator (PI) with qualification and designation
6. Name of the Co-investigator(s) (Co-PI) with qualification and designation
7. Duration of the Project
8. Source of funding & financial allocation for the project / trial
9. Has subject recruitment begun?
10. If subject recruitment has not begun, give reasons and proceed to No:20
11. How many subjects have been screened?
12. How many subjects have been recruited?
13. How many more to be recruited
14. Is subject recruitment continuing?
15. Are there any 'drop outs'?
16. Are subjects still receiving active intervention?
17. Have there been any adverse events? If yes, give details
18. Have there been any Serious Adverse Events adverse events? If yes, give details.
19. Have there been any unanticipated study-related problems?
20. Is there any new risk or benefit information? If yes, give details.
21. Are there any interim changes to the protocol or consent form? If yes, give details including submission of revised protocol and consent form for approval
22. Does the scientific literature indicate changes in knowledge relevant to the conduct of the study?
23. List of attachments for review, if any
24. Remarks, if any
25. Signature of the Principal Investigator with date.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal.

Institute Ethics Committee, KIDS, Bangalore

Format for *submission of revised/additional documents, protocols and information regarding already approved projects* to be submitted by the Principal Investigator (PI) (Two copies of this form along with the revised documents to be submitted)

1. IEC Reference No:

2. Approval Date and Number:

3. Title:

4. Principal Investigator:

5. Purpose of this submission:

6. New documents being submitted: Please list the documents being submitted along with the differences from the previously approved documents in a tabular form as below:

S. No.	List of Documents being submitted	List the modifications/revisions made from previously approved proposal, wherever applicable

Place:

Date:

Signature PI/Collaborator _____

Name:

Six monthly progress of Project

Institute Ethics Committee Reference No. _____

Study title: _____

Name of the Principal Investigator _____

Designation / Department _____

Duration of Study _____

Date of Starting of the Study _____

Period of Six monthly progress report: from _____ to _____

Progress:

Side Effect if any:

Amendments if any:

Discontinuation reasons:

Progress:

Signature of Principal Investigator _____

Date: _____

PARTICIPANT INFORMATION SHEET (PIS)

The project must be accompanied by the Participant information sheet addressed to the patient or participant or parent/ guardian, in case of minor. While formulating the participant information sheet, the investigator must provide the subjects with the following information in **English and Hindi/Kannada, in a simple layman's language which can be understood by them, in a narrative form, directed to the participant/ LAR, covering all the points:**

1. Study Title
2. Aims and methods of the research study
3. Expected duration of participation
4. The benefits to be expected from the research to the participant or to others
5. Any risk or discomfort to the participant associated with the study
6. Maintenance of confidentiality of records
7. Provision of free treatment for research related injury
8. Compensation of subjects for disability or death resulting from such injury
9. Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would be entitled otherwise
10. Amount of blood sample (quantity in tea spoon full) to be taken
11. Costs and source of investigations, disposables, implants and drugs/ contrast media
12. Telephone number/ contact number of Principle investigator and Co-Investigator at the top of each page
13. In case of a drug trial:
 - a. The chemical name of the drug, date of its manufacturing and batch number must be mentioned
 - b. Initial bioequivalence study of the drug/ references should be provided
14. Self-certification should be given that the translation to vernacular language is correct

PARTICIPANT INFORMED CONSENT FORM (PICF)

Protocol Study number: _____

Patient identification number for this study: _____

Title of the project: _____

Name of Principal investigator:

Tel. No (s).

The contents of the information sheet dated_ _____ that was provided have been read carefully

by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from KIDS-B. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

(Signatures / Left Thumb Impression)

Date:
Place:

Name of Participant: _____ Son/Daughter/spouse of: _____

Complete postal address: _____

This is to certify that the above consent has been obtained in my presence.

Signatures of the Principal Investigator

Date:
Place:

1) Witness – 1**2) Witness – 2**-----
Signature-----
Signature

Name:

Name:

Address:

Address:

NB: Three copies should be made, one each for (1) Patient (2) Researcher (3) Institution (Investigators are advised to prepare the translation in simple understandable Hindi/ Kannada on their own)

सहभागी सुचित सहमति प्रपत्र

इस जाच के लिए सहभागी पहचान नमबर _____
 अनुसन्धान शीर्षक _____
 मुख्य अन्वेषक का नाम _____ फोन नंबर: _____

मैंने दिनांक _____ के सूचना पत्र में दिये गए सभी तथ्यों को पढ़ लिया है। मुझे समझ आने वाली भाषा में विस्तारपूर्वक बतला दिया है और मैंने तथ्यों को भली भांति समझ लिया है। मैं पुष्टि करता हूँ कि मुझे प्रश्न पुछने का अवसर दिया गया है।

मुझे अध्ययन की प्रकृति, उद्देश्य और इसके सम्भावित लाभ/जोखिमों और अध्ययन की सम्भावित अवधि अन्य प्रासंगिक जानकारी के बारे में विस्तार पूर्वक समझा दिया गया है। मैं समझता हूँ कि इस अध्ययन में मेरी भागिधारी स्वैच्छिक है और इस अध्ययन से किसी भी समय बिना कोई कारण बताए, बिना मेरी चिकित्सा देखभाल या कानूनी अधिकारों के प्रभावित हुए अपना नाम वापिस ले सकता/सकती हूँ।

मैं समझता हूँ कि इस अनुसन्धान में मेरी सहभागिता से मेरे बारे में एकत्र जानकारी और चिकित्सीय नोटों को एम्स अस्पताल के जिम्मेदार लोगो द्वारा देखा जायेगा। मैं इन व्यक्तियों को अपने रिकॉर्ड देखने कि अनुमति प्रदान करता/करती हूँ।

मैं उपयुक्त अध्ययन में भाग लेने के लिए अपनी सहमति प्रदान करता /करती हूँ।

सहभागी के हस्ताक्षर / बाएं अंगूठे का निशान	दिनांक	स्थान
सहभागी का नाम		
पिता/पति का नाम		
पूरा पता		

यह प्रमाणित किया जाता है कि उपयुक्त सहमति मेरी उपस्थिति में ली गई है।

मुख्य अन्वेषक के हस्ताक्षर	दिनांक:	स्थान:
१) गवाह के हस्ताक्षर	२) गवाह के हस्ताक्षर	
नाम	नाम	
पता	पता	

Data Elements for reporting serious adverse events occurring in a clinical trial

1. Patient Details

Initials & other relevant identifier (hospital/OPD record number etc.)*
Gender
Age and/or date of birth
Weight
Height

2. Suspected Drug(s)

Generic name of the drug*
Indication(s) for which suspect drug was prescribed or tested
Dosage form and strength
Daily dose and regimen (specify units - e.g., mg, ml, mg/kg)
Route of administration
Starting date and time of day
Stopping date and time, or duration of treatment

3. Other Treatment(s)

Provide the same information for concomitant drugs (including nonprescription/OTC drugs) and non-drug therapies, as for the suspected drug(s).

4. Details of Suspected Adverse Drug Reaction(s)

Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.*

Start date (and time) of onset of reaction
Stop date (and time) or duration of reaction
Dechallenge and rechallenge information
Setting (e.g., hospital, out-patient clinic, home, nursing home)

5. Outcome

Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted

For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; Any post-mortem findings.

Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.

*6. Details about the Investigator**

Name
Address
Telephone number
Profession (specialty)

Date of reporting the event to Licensing Authority:

Date of reporting the event to Ethics Committee overseeing the site:

Signature of the Investigator

*Note: Information marked * must be provided.*

**KLE Society's Institute of Dental Sciences, Bangalore
Institutional Ethics Committee Review Form**

Serial No of IEC (to be filled by IEC Office):

-----To be filled by Investigators-----

Proposal Title:

Principal Investigator:

Co-investigator: 1.
2.
3.

Supporting Agency: ICMR/ non ICMR

If non ICMR, name of agency:

-----To be filled by reviewer-----

Project Status: New Revised

Review: Regular Interim

Date of Review:

1. Research Design

- | | | | |
|------|--|------------------------------|-----------------------------|
| i. | Scientifically sound enough to expose subjects to risk | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| ii. | Relevant to contribute to further knowledge | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| iii. | Of national importance | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

2 Risks

- | | | | |
|----|---|-------------------------------------|---------------------------------------|
| a. | Is there physical/social/psychological risk/discomfort? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| b. | Is the overall risk/benefit ratio | Acceptable <input type="checkbox"/> | Unacceptable <input type="checkbox"/> |

3 Benefits

- | | | | |
|-----------|---|------------------------------------|-------------------------------|
| Direct: | Reasonable <input type="checkbox"/> | Undue <input type="checkbox"/> | None <input type="checkbox"/> |
| Indirect: | Improvement in science/knowledge <input type="checkbox"/> | Any other <input type="checkbox"/> | |

4 Subject selection :

- i Inclusion / exclusion criteria addressed? Yes No
- ii Vulnerable subjects (woman, child, mentally challenged, seriously or terminally ill, foetus, economically or socially backward and healthy volunteers) adequately protected ? Yes No
- iii. Special group subjects (captives, students, nurses & dependant staff) adequately protected? Yes No

Privacy & Confidentiality maintained? Yes No

Patient Information Sheet: Adequate Inadequate

7. Consent form components addressed adequately? Yes No

8. Compensation, (if applicable) addressed adequately? Yes No

9. Is there a Conflict of Interest? Yes No

If yes, Acceptable Unacceptable

10. Budget: Appropriate Inappropriate

11. Decision of review
Recommended Recommended with suggestions
Revision Rejected

Any other remarks/suggestions:

Reviewers names and Signatures

KLE Society's Institute of Dental Sciences, Bangalore

Communication of Decision of the Institutional Ethics Committee (IEC)

(Fields 1,2 and 3 to be filled by investigators)

IEC No:

1. Protocol title
2. Principal Investigator:
3. Name & Address of Institution:
<input type="checkbox"/> New review <input type="checkbox"/> Revised review <input type="checkbox"/> Expedited review
Date of review (D/M/Y): Date of previous review, if revised application:
Decision of the IEC/ IRB: <input type="checkbox"/> Recommended <input type="checkbox"/> Recommended with suggestions <input type="checkbox"/> Revision <input type="checkbox"/> Rejected
Suggestions/ Reasons/ Remarks:
Recommended for a period of :

Please note *

- **Inform IEC immediately in case of any Adverse events and Serious adverse events.**
- **Inform IEC in case of any change of study procedure, site and investigator**
- **This permission is only for period mentioned above. Annual report to be submitted to IEC.**
- **Members of IEC have right to monitor the trial with prior intimation.**

Principal
K.L.E Institute of Dental Sciences

Chairman
IEC

Member Secretary
IEC

NAME, QUALIFICATION, ADDRESS & SPECIALTY OF MEMEBERS OF ETHICS COMMITTEE

No	Name	Qualification	Address	Contact No.	Fax No.	e-mail ID	Specialty
1	Dr. Vijayalakshmi I. Balekundri	M.B.B.S, M.D, D.M (Cardio) , DSc.	Aditi, 44 A, V Main Road, Vijayanagar,II stage,Hampinagar, Bengaluru-560 040	9448494084	nil	docvj@yahoo.com	Chairperson/ Cinician (Pediatric Cardiologist) Non institutional
2	Dr.Ashwin Prabhu	MDS	Flat 105, Bindiya residency, 24 th Main, 6 th Phase , JP Nagar, Bangalore-560078	9845011615	nil	Prabhu.ash@gmail.com	Member Secretary/Clinician
3	Dr. Sudhir R Patil	MDS	Flat S3-Block B, No.36-39, Reliance Mansions, Hariram Aildas Layout, Vijaynagar, Bangalore -560040	9845560110	nil	zonaperio@gmail.com	Clinician
4	Dr Sandhya Devi Patil	MDS	Flat S3-Block B, No.36-39, Reliance Mansions, Hariram Aildas Layout, Vijaynagar, Bangalore -560040	9845551803	nil	Sandy_oct@rediffmail.com	Clinician
5	Dr. Sumitra	MDS	2921E, I cross road, II stage, Vijaynagar Bangalore-40	9448388716	nil	sumayjr@gmail.com	Clinician
6	Mr. Gundu Rao H L	Dip. In Craftsmanship	#612, 3 rd cross,2 nd stage A block, RHCS Layout, Srigandhada kavalu, Bangalore -91	9845216591	nil	Gundurao.hl@gmail.com	Social Worker (Non Institutional)
7	Mrs. Nancy Suresh Shetty	B.A, L.L.B(M.A) LLM	No.23, Anantharam Layout, 6 th cross, Lingarajpuram, St. Thomas Town, Bangalore-84	9845214486	nil	nancyprince@rediffmail.com	Legal expert (Non Institutional)
8	Mr. Madhusudhan G	B.A, M.A, B.Ed, M. Phil.	#19/19 4 th cross, Bapuji Layout, Vijaynagar , Bangalore -560040	9986368438	nil	Madhusudhan.kle@gmail.com	Social Scientist/ Philosopher

9	Dr. Shyla V.	MBBS, MD (Path), PGDHHM	AVIGHNA", #32, 3rd A cross, 2nd stage Satyanarayaa layout, JCNagar, Bangalore - 560086	9980095894	nil	shylaramesh@yahoo.com	Pathologist/Basic Medical Scientist
10	Mr. Chidananda S Kanade	BA	No.101, 12 th Cross, 1 st K block, rajajinagar, Bangalore -10	9945388224	nil	chidanandkanade@gmail.com	Lay Person from community

DETAILS OF SUPPORTING STAFF

Sl No.	Name	Designation
1.	Smt. Rashmi Patil	Clerk/Typist
2.	Mr. Kanti	Peon

CURRICULUM VITAE

Name : **Dr. VIJAYALAKSHMI I. BALEKUNDRI**

Nationality : **Indian**

Date of Birth : **6th August, 1950**

Place of Birth : **Belagavi, Karnataka**

Present Designation : **Former Professor of Pediatric Cardiology**

Place of Work : **Sri Jayadeva Institute of Cardiovascular Sciences and Research, Bengaluru**

Mailing Address : **Aditi, 44 A, V Main Road,
Vijayanagar II stage, Hampinagar,
Bengaluru-560 040**

E-mail : **docvj@yahoo.com**

Mobile no : **9448494084**

Karnataka Government : **Joined Govt. Service on 25th September, 1974.
Served in various hospitals as doctor**

Teaching Experience : **Teacher for undergraduates, post graduates,
MD, DNB students in Pediatrics, Medicine,
Fellowship in Pediatric Cardiology
DNB and DM Cardiology students**

Accreditation Inspector : **MCI, NBE, RGUHS.**

**Member of Speciality Advisory National Board of Examinations Board in
Cardiology**

Senate Member : **Rajiv Gandhi University of Health
Sciences, Bangalore - 2000-2003.**

Governing Council Member: **JSS Medical College ,Mysore.
PES University 2014**

Qualification : **MBBS - Karnatak University, 1973
MD in Gen Medicine -1977 and
DM in Cardiology -1992,
Bangalore University
DSc. Womens University, Bijapur**

Dr. Vijayalakshmi I. Balekundri, MBBS, MD, DM (Card), DSc, FICC, FIAMS, FIAE, FICP, FCSI, FAMS. has been working as Professor of Pediatric Cardiology at the premier cardiac centre of India, Sri Jayadeva Institute of Cardiovascular Sciences and Research, Bengaluru. She has had a brilliant academic career stood first to Bangalore University in MD (Gen. Medicine) and secured Dr. K.S. Shadaksharappa Gold medal in 1977. She is the **first Lady Cardiologist of Karnataka**. She is the first one to head the department of Paediatric Cardiology in Karnataka on 14th November, 1998 (Children's day). She is a pioneer in interventions in Paediatric Cardiology and did the first Amplatzer device closure in Karnataka, highly talented and has earned a name as a skilled interventional Paediatric Cardiologist. She has had a brilliant academic career and has been awarded **33 gold medals and 2 silver medals**. She has been an excellent teacher for three decades and has taught undergraduates, postgraduates, post doctorate students (DM cardiology). She has been an examiner for National Board Fellowship in Pediatric Cardiology. She is an **accreditation inspector for MCI and NBE for MD, DM and DNB (Cardiology)**. She has done pioneering work in interventions and device closure in children. She has **140 research** papers out of which 45 are international with 100 total citations and **citation index of 16.7**. She has **82 publications** including **4 text books** for the cardiologists, that includes monogram on “**Acute Rheumatic fever and Rheumatic heart Disease**” and book on “**Step by step to Echo in Congenital Heart Disease**” She is the chief Editor of a Text book on-“**A Comprehensive Approach to Congenital Heart Disease**” (a lifelong Odyssey) for which the book review has been written by **Dr. Crystal R. Bonnichsen, of Mayo clinic and published in European heart journal**. She has edited -**Cardiac catheterization and Imaging from Pediatrics to Geriatrics**. She has set **seven world records**. She is the first person in the world to close both aorto- left ventricular tunnel and aorto- right ventricular tunnel with device. She has set a record by closing the largest PDA (8.6 mm) in the smallest infant (4.5 kg) for the first time with angled device in the world. For the **first time in the world**, she has proposed and published “**Vijaya's Echo criteria**” for the early and precise diagnosis of Carditis in children with Acute Rheumatic fever. Her study has been quoted in latest editions of standard Pediatric Cardiology Textbooks like ‘Heart Diseases in Infants and Children' by Moss and Adams' and Park's Pediatric Cardiology for Practitioners 5th edition. She is the only Indian to deliver 6 guest lectures and one oral paper at the World Congrress of Pediatric cardiology at Cape Town South Africa, 2013. She has delivered **23 orations, (got Standing ovation 4 times)** including the **most prestigious G.S Sainani oration and Prof. K. K. Datey Memorial Oration** at the National Conference of API and CSI respectively.

She has bagged the **best presentation award six times** 1) Low blood pressure truth or myth at state CSI-API conference 1992. 2) Best presentation at World Congress of Paediatric Cardiology at Toronto, Canada 2001. 3) 1st prize for outstanding scientific presentation at **World Congress of Echocardiography** at New Delhi 2002. 4) Balloon valvuloplasty for Critical Aortic Stenosis: Initial results and Mid-term follow up at 56th National CSI 2004 at Bengaluru. 5) Best presentation award at PICS 7 AICS International conference at **Chicago in July 2010, and 6) for ‘My Nightmare Case in the Cath Lab’ in 2011 at Boston.**

She was given a civic reception at **Minnesota USA in 1998**, Awarded Dr. B.C. Roy Doctors Day Award 2004 by IMA CHS, Bangalore. Awarded Professor Pa. Gu. Hallakatti Puraskara for 2005. ‘Vocational Excellence Award’ for eminent personalities by Rotary club Bangalore, 2005. Chanakya Kautilya Global Indian Award 2006’ for recognition of distinguished and outstanding excellence in Medicine - December 2006. “Kaayaka Shree Prashasti” 2007, “Kadali Prashasti” 2007, Smt Savithramma De Jaware Gowda “Vishwa Maanava Prashithi” at Mysuru 2007. “World congress-2008 Lifetime Achievement Award for outstanding contribution in the field of Clinical and Preventive Cardiology” from **Bharat Ratna His Excellency Dr. A.P.J. Abdul Kalam (Former President of India)**, **Rajya Bhushana award from Bharatha Yuva Kendra**, received highest state award- **Rajyotsava Award 2008**, She has been conferred with titles “**Rajya Rathna**” 2008, **Mythic Society award 2009, WCCPGC-2009 Lifetime Achievement Award**” for “**Outstanding Contribution in the field of Cardiology in the World**”, from her excellency **Smt Pratibha tai Patil**, then President of India, **Sri Renukacharya Shree 2010 and Lifetime Achievement Award-2010**” from **Smt Sheila Dixit** Hon.Chief Minister, New Delhi, Award of excellence in the field of Cardiology in the world from **Sri Ghulam Nabi Azad**, Hon. Union Minister of Health and Family Welfare, India, in September 2011 on World Heart Day. She is a recipient of prestigious “**Siddaganga Shivakumar Shri**” 2012 “**Sudnyaana Varshini**”-2012, “**Sharana Ratna**” -2012 , “**Lipi Pragne**”- 2012. “**Vaidya Shri**”- 2013, “**Vishwa Maanava**”-2013 and **Vishwa Shri-2013**, **Shoonya Peetha Akka Prashsti-2013** and Jawaharlal Nehru Gold Medal 2014. Life time achievement award in Echocardiography by **Chief Minister of Madhya Pradesh-2014**. 2015 - Padma Made Gouda Mahila Seva Prashasthi., Mahadevi Akka Prashasthi, **Basava Shiromani Prashasthi, Pride of Karnataka** 2015.

She is the first lady President of Cardiological Society of India, Karnataka Chapter, and also Bengaluru chapter and President, Indian Academy of Echocardiography, Karnataka chapter. She has been awarded Hon Doctorate of science (DSc) for outstanding contribution in the field of Science and technology by the Karnataka state women’s University. As a Convener of Congenital Heart

Disease of CSI, India, she has **proposed the “National Policy for Congenital Heart Disease”**. Presently she is the Convener of CHD sub specialty chapter of CSI India. She has received the prestigious fellowship from **National Academy of Medical Science (FNAMS)**. She is a very popular columnist in Kannada dailies, She is a crusader against the social evils like Tobacco and Alcohol among the students and also written books and booklets for the public in Kannada to bring awareness. One of her articles is published in **X std Kannada text book**. Her achievements are material for the Phd thesis on women achievers in Karnataka. The government of Karnataka has made a documentary on her. She was shortlisted for Vice Chancellor post twice. She was an organizing secretary of unique World congress of Cardiology in which the theme was Spirituality and Science hand in hand. She has served as **Senate member of Rajiv Gandhi University of Health Sciences, Bangalore - 2000-2003**.

She is compassionate to the poor, service oriented and has developed the field of Pediatric Cardiology in Karnataka and popularized interventions (treatment without surgery, without scar on the chest). She has also done great service in the field of continuing medical education as a life member of Medical education trust, Bengaluru. She is known to serve the patients honestly and sincerely with the missionary zeal.

1. ACADEMIC DISTINCTIONS

- a) **All round best outgoing student** of the year 1967, RL Science Institute, Belagavi.
- b) Stood **first in MD** (General Medicine), Bangalore University & secured **Dr. K. S. Shadaksharappa GOLD MEDAL**.
- c) **First qualified Lady Cardiologist of Karnataka**
- d) **First to start the department of Paediatric cardiology in Karnataka**
- e) Won best paper API award for “Low Blood Pressure Truth or Myth” at Bellary Conference in 1991.
- f) Mechanism of functional MR in DCM, effect of Ramipril presented for Searle award at 47th CSI National conference, Lucknow in 1995.
- g) High point in her career is the **Grand rounds at Minnesota University, USA**, where she spoke on “Changing Profile of Acute Rheumatic Fever- The need to include Echo criteria for diagnosis” in 1999.
- h) **Awarded prize for presentation “My Nightmare case in Catheterization Laboratory” at PICS-V, 2001 at Toronto, Canada.**

- i) **First prize for outstanding scientific paper on “Is there a need to include ECHO in Jones’ criteria for diagnosis of Acute rheumatic fever” at 6th World Congress of Echocardiography & Vascular Ultrasound, New Delhi in February, 2002.**
- j) **Delivered 22 orations including the most prestigious G.S Sainani oration and Prof. K. K. Datey Memorial Oration** at the National Conference of API and CSI. respectively. First and the only **Kannadiga** to deliver these orations in 57 years.
- k) As a Convener of Congenital Heart Disease of Cardiological Society of India, **for the first time in independent India** she has **proposed the “National Policy for Congenital Heart Disease”** She was also the Sub speciality, convenor of Acute rheumatic fever and Rheumatic Heart Disease of CSI. She is presently the CSI convenor of Sub speciality, of Pediatric Cardiology.
- l) For the first time in the world, she has proposed and published **“Vijaya’s Echo criteria”** for the early and precise diagnosis of carditis in children with Acute Rheumatic fever in **“The efficacy of echocardiographic criterions for the diagnosis of carditis in acute rheumatic fever”**. *Cardiol Young* 2008 published by Cambridge University. This paper was recommended for global reading by Dr. Alwi
- m) She had the honour of delivering a guest lecture on **‘Progress of Paediatric Cardiology in Indian Subcontinent’** at Kuala Lumpur in June 2004.
- n) **Best Paper award at PICS and AICS conference at Chicago in July 2010**
- o) **Best Paper award at PICS and AICS conference at Boston in July 2011**
- p) Her studies has been quoted in the latest editions of standard Pediatric Cardiology Textbooks like **“Moss and Adams’ Heart Diseases in Infants and Children”** and **“Park’s Pediatric Cardiology for Practitioners”** 5th edition and in **Critical care of children with heart disease** by Tissot, 2010.
- q) Presently on **Panel for International Standardisation of Echocardiographic Diagnosis of Rheumatic Heart Disease** in collaboration with World Heart Federation.
- r) Author and editor of **textbooks – 1) Step by Step – Echocardiography in Congenital Heart disease, 2) Acute Rheumatic Fever and Rheumatic Heart Disease, 3) A comprehensive approach to congenital heart diseases (2013). 4) Cardiac catheterization and Imaging – 2015**
- s) Brilliant academic career and has been awarded **33 gold medals.**
- t) Has more than **62 publications** in both international and national journals

- u) Has presented more than 130 **research papers** in both international (40) and national conferences both in India and abroad.
- v) Has delivered more than 450 **academic lectures** at state, national and international conferences.
- w) Excellent **teacher** for three decades and has taught undergraduates, postgraduates, post doctorate students (DM students). She teaches paediatric cardiology to paediatric post graduates from all the medical colleges in Karnataka.
- x) Chairman reviewer and Examiner for DNB Fellowship in Pediatric Cardiology from 2006 and Chairman and Examiner for Fellowship in Pediatric Cardiology for RGUHS from 2007 till date.
- y) Reviewer for International journals - Echocardiography and Cardiology in the Young and for National journals.
- z) **Pioneer in Paediatric Cardiology and has earned a name as a skilled interventional Paediatric Cardiologist and has done more than 8600 catheterisations with a lot of firsts to her credit both at international and national level.**

2. AWARDS

1. Awarded civic reception art USA Minnesota , USA in 1999.
2. Awarded Dr. B.C. Roy Doctors Day Award 2004 by IMA CHS
3. Professor Pha.Gu.Hallakatti Puraskara for 2005
4. ‘Vocational Excellence Award’ for eminent personalities by Rotary – Bengaluru, 2005
5. Distinguished Career Award – Dr. Vijaya Sreenivas Memorial Award from SASAT in October 2006
6. Chanakya Kautilya Global Indian Award 2006’ for recognition of distinguished and outstanding excellence in Medicine - December 2006.
7. Kaayaka Shree Prashasti 2007
8. Kadhali Prashasti 2007
9. Smt Savithamma De Ja Gou “ Vishwa Maanava Mahila Prashithi” at Mysore 2007
10. Vocational Excellence from Rotary club ,Tumkur 2008
11. WCCPGC- 2008 Lifetime Achievement Award for outstanding

- contribution in Cardiology in the World from Her Excellency Mrs. Pratibha Devi Singh Patil, Hon'ble President of India- 2008
11. "World Congress Clinical Preventive Geriatric Cardiology-2008 Lifetime Achievement Award for outstanding contribution in the field of Clinical and Preventive Cardiology" from Bharat Ratna His Excellency Dr. A.P.J. Abdul Kalam (Former President of India)
 12. Awarded 100 dollars prize for "Vishwa Aarogyakke Karnatakada Sharanara Sandesha" at AKKA, Chicago, USA
 13. Rajya Rathna 2008 from Bharatha Yuva Kendra
 14. Awarded the highest state award – "Rajyotsava Prashasthi" in 2008
 15. 'Rajya Bhushana Prashasthi' 2009
 16. Mythic Society 2009
 17. WCCPGC-2009 Lifetime Achievement Award" for "Outstanding Contribution in the field of Cardiology in the World"
 18. Sri Renukacharya Shree Prashasti in 2010
 19. Karnataka Padmashree in 2010
 20. Lifetime Achievement Award-2010" from Smt Sheila Dixit, Hon. Chief Minister , New Delhi in October 2010.
 21. Award of excellence in the field of Cardiology in the world from Sri Ghulam Nabi Azad, Hon. Union Minister of Health and Family Welfare, India, in September 2011 on World Heart Day.
 22. Honorary doctorate in Science and Technology(DSc) from women's University,Bijapur,- 2012.
 23. Vishwa Shree Award -2012
 24. Sudnyaana Varshini prashasti -2012
 25. Sadbhaavana Award- 2012
 26. Sharana Ratna Prashasti -2012
 27. Siddaganga Shivakumar Shri Prashithi-2012
 28. Lipipragne -2012
 29. Vanchanashree -2012
 30. Vaidayashree - 2013.
 31. Shoonya Peetha Akka Prashsti-2013

32. Jawaharlal Nehru Gold Medal- 2014
33. Padma Made Gouda-2014
34. Mahila Seva Prashasthi- 2015
35. Mahadevi Akka Prashasthi-2015
36. Basava Shiromani Prashasthi -2015
37. Pride of Karnataka- 2015.

3. FIRST IN THE WORLD

- a) For the First time in the **world** a case of Non-Compaction of Left Ventricle with the Aorto left ventricular tunnel closed with Amplatzer device in 2001. **Presented at 37th Annual Scientific meeting & AGA Medical 4th International Symposium at Porto, Portugal, 15th to 18th May, 2002 and published in Pediatric cardiology,USA,2004.**
- b) For the First time in the **world** a case of Isolated Dextrocardia with midmuscular VSD to be closed with Amplatzer device in 2001 **Presented at 37th Annual Scientific meeting & AGA Medical 4th International Symposium at Porto, Portugal, 15th to 18th May, 2002.**
- c) For the First time in the **world a case** of PDA larger than aorta in a 4.5 kgs infant closed with Amplatzer angled PDA device and published in Pediatric cardiology, USA in 2003.
- d) For the First time in the **world** a case of large PDA in a 3.9 kgs infant to be closed with modified Amplatzer device in 2003. **PICS-VI at Chicago, USA between 22-25th September, 2002 and published in Pediatric cardiology,USA,2004.**
- e) For the First time in the world a case of sickle cell anemia with ASD was closed with device closure Presented in world congress, Argentina in2005.
- f) For the First time in the **world a case** of left coronary cameral fistula to RV closed with ADO II in 2011. Published in J invasive cardiology May 2013.(This topped the list of top publications of 2013)
- g) For the First time in the **world a case** of Aortico right ventricular tunnel closed with ADO II. Published in J invasive cardiology April 2013.

4. FIRST IN INDIA

- a) First cases of PDA closure done in India with Nit Occlud in 2002.
- b) Aortic balloon valvuloplasty done in a case of Hydrops foetalis (14 hours old newborn, wt 2.5 kgs). Youngest in the country to undergo valvuloplasty in 2007

5. FIRST TIME IN KARNATAKA

- a) First successful Aortoplasty for coarctation of Aorta done in 1990.
- b) First case of transradial catheterisation done in 1995.
- c) First case of PTMC by Joseph Balloon done in 1999.
- d) First case of ASD Closure by Amplatzer Device done in 1999.
- e) First case of PDA closure by Amplatzer Duct Occluder done in 1999.
- f) First neonate (2.5 kgs) to undergo balloon valvuloplasty in SJIC,1999.
- g) Successful Aortic balloon valvuloplasty done a in 14 days neonate wt 1.8 kgs in 2007.
- h) Successful closure of a large PDA in 5 kgs infant with new Amplatzer duct occluder (ADO II).
- i) Successful Aortic balloon valvuloplasty for aortic stenosis and PTMC for mitral stenosis in a case of Dextrocardia with situs inversus 2012

6. Only Indian and the only woman to do a live case demonstration at IJN Live 2004 at Kuala Lumpur, Malaysia.

7. Only Doctor from Karnataka to deliver grand rounds in Fairview University Children's Hospital (Minneapolis), USA in 1999

8. EXPERIENCE IN PAEDIATRIC CARDIOLOGY

1. Trained at Escort's Heart institute, New Delhi in 1998.
2. Trained at All India Institute of Medical Sciences, New Delhi in 1998.
3. **Trained in USA in 1999**
 - a) **Fairview University Children's Hospital (Minneapolis)**
 - b) St. Mary's Hospital (Rochester), **teaching hospital of Mayo Clinic Medical School.**
 - c) Children's Hospital Medical Centre (Boston, Massachusetts), **teaching hospital of Harvard University.**
 - d) Trained at Children's Hospital at Chicago University in 2002.
9. Total Cardiac Catheterisations in children done more than **7300**

10. ORATIONS (Totally 23)

- 1). 'Newer and Novel Methods of Management of Cardiovascular Diseases' for **Shashidhar Maalaka Raddy Gold Medal Oration**' during XIX Joint Kapicsicon 2001 & South Zone Apicon 2001 at Mangalore on 20.5.2001.
- 2). 'Paediatric Interventions' : Bird's eye view of our experience". **Sri P.M. Nayak Memorial CSI Oration** and Gold Medal lecture on 14.7.2002 during the 1st Annual Conference of CSI of India, Karnataka Chapter at Bangalore.

- 3). 'Clinical approach to the diagnosis of Cyanotic Congenital Heart Disease and Recent Advances in non-surgical management of CHD' on 31.7.2002 for the (Dr B.S Panduranga) Memorial silver medal lecture during the CME programme in Internal Medicine at IMA auditorium, Bangalore.
- 4). 'Evolution of Paediatric Cardiology – Current Scenario of Interventions **Prof. K.K. Datey Memorial Oration** during the 54th Annual CSI Conference at Kochi on 4.12.2002.
- 5). "Interventions in Cardiology from Pediatrics to Geriatrics" for **Dr.V.G.Nadagouda Honour lecture** on 10.5.2003 at KAPICON 2003, Mysore.
- 6). 'Paediatric Cardiology – Yesterday, Today & Tomorrow' for **Paediatric Heart Foundation Oration** at the 2nd Annual Conference of CSI of India, Karnataka Chapter at Belgaum on 7.9. 2003.
- 7). 'Interventions in Pediatric Cardiology at the turn of the century – New Horizons' for CSI, **Presidential Oration** during the 3rd Annual Conference of CSI Karnataka Chapter and Karnataka Association of Cardiovascular and Thoracic Surgeons held in Mangalore on 2.9.2005.
- 8). 'Interventions in Cardiology from Womb to Tomb' **Dr. Sainani Oration** during APICON 2006 at Patna on 31.1.2006.
- 9). 'Rheumatic Fever- Why still a burning problem?' **Dr. K.Shadakshrappa Oration 2006** during the MERT CME programme of Internal Medicine at Bangalore on 12.10.2006.
- 10). 'Can echocardiography change the epidemiological face of rheumatic fever and rheumatic heart disease' for the **Dr. K.Shadaksharappa Memorial Oration 2008 during the Annual API conference** at Bangalore.
- 11). 'Pediatric Cardiac interventions as adjunct to Pediatric Cardiac surgery' CSI, **Presidential Oration** during the Annual Conference of CSI Bengaluru Chapter in Belagaum on 18.10.2008 .
- 12). Oration at WCCPGC 2009 – Role of Echocardiography in changing the epidemiological face of Rheumatic fever and heart disease"
- 13). Oration at WCCPGC 2010 – 'Interventions from Womb to Tomb"
- 14) Interventions from womb to tomb – **IMA oration, Dharwad**, in Sept-2012
- 15) Echo guided pediatric cardiac interventions for **Dr Parashar oration** at the WCCPGC 2012 at Mount Abu.
- 16) **Natesa G Pandian oration**. Role of Echocardiography in detecting chicken heart in humans at Annual conference of IAE at Chennai 2012.
- 17) **Naveen C Nanda Oration** at WCCPGC 2013, JSS, **Suttur** in September 2013.
- 18) **IMA Belgaum branch Oration** May 2014.

19) **Amalananda Das Memorial Lecture** at 66th Annual Conference of CSI-2014, Hyderabad - The Efficacy Of Echocardiographic Criteria For The Diagnosis Of Carditis In Acute Rheumatic Fever.

20) **Nirmala Kesari oration** Diagnosis and Management of Acute Rheumatic Fever - 2015 at Davangere 2015.

21) **IMA-KSB Endowment Oration** at 81st IMA Karnataka State Annual Medical Conference MEDICON- 2015, VIJAYAPURA - Long Journey of Jones Criteria -Importance of Echocardiography

22) **Naveen C Nanda Oration at WCCPCCI – Mount Abu, 2015** - Echocardiography in RHD: New Frontiers 2015.

23) **Dr Shankaragoud Amarked Memorial oration** at Physician's day. API in December 2015

11. BEDSIDE CLINICS TAKEN FOR PG'S IN VARIOUS MEDICAL COLLEGES

1. J.S.S Medical College, Mysore on 5.2.95.
2. Bellary Medical College, Bellary on 7.7.96.
3. For Gynec. Ob. PG's at Cheluvamba Hospital on 24.8.96.
4. For MD Paediatrics students, Mysore Medical College 24.8.96.
5. For MD Paediatrics and Medical Students, JNMC, Belgaum on 7.6.2000.
6. Bedside clinics for PG students of **Sri Ramachandra Medical college, Porur, Chennai 2001**
7. For postgraduates - Bedside clinics and ECHO demonstration at Devaraj Urs Medical College, Kolar on 8.3.2001.
8. For DM Cardiology students and conducted workshop at **CMC Vellore**, January, 2002.
9. Bedside clinics and ECHO demonstration at Bellary Medical College on 24.8.2002.
10. Bedside clinics on CHD at Bellary Medical College on 4.9.2004.
11. Bedside clinics and ECHO demonstration at Devaraj Urs Medical College, Kolar on 1.3.2005.
12. Bedside clinics for PG students of **Tirupathi Medical College, Tirupathi 2004**
13. Bedside clinics for PG students of BMC, Bangalore on 25.5.2007.
14. Bedside clinics for PG students of MR Medical college Gulbarga on 29.10.2007.
15. Bedside clinics for PG students of Bapuji Medical College, Davangere on 11.4.2008.
16. Bedside clinics for PG students of Adichunchigiri College, Bellur, 2009.
17. Bedside clinics for PG students of Alameen Medical College, Bijapur, 2009.
18. Bedside clinics for PG students of KIMS, Hubli on October, 2010.

19. Bedside clinics for PG students Gulbarga Medical College, 2010
 20. JNMC Belgaum for MD and DM students 2014

EDUCATIONAL DETAILS

Pre medical Education	R.L.Science Institute Belgaum: All round best out going student 1967	Pre University	1966-1968
Medical College Education	Karnataka Medical College, Hubli	M B B S	1968-1973
	Bangalore Medical College	M D Gen Med.	1974-1977
	Sri Jayadeva Institute of Cardiology	D M Cardiology	1989-1992
Medical Education	Karnataka Medical College Hospital - various Departments	Rotating Housemanship 1972-1973	1 Year
	Post graduate in Gen Medicine	1974	1 st Year
	Post graduate in Gen Medicine	1975	2 nd Year
	Post graduate in Gen Medicine	1976	3 rd Year
	Resident Physician	1977	
Graduate Degree	M B B S	1968-1972	
Post graduate degree	M D(Internal medicine)	1974-1977	
PostDoctoral Degree	D M (Cardiology)	1989-1992	

**List of all past & present Hospital appointments.
 Medical Society Membership & Fellowships**

	Name of the Hospital	Staff Position	Specific Year
1	K M C Hubli, Karnataka	Assistant Surgeon	1974-1976
2	Victoria Hospital, Bangalore Medical College	Assistant. Surgeon	1976-1977
3	K M C Hubli, Karnataka	Resident Physician	1977-1981
4	E S I Hospital Rajajinagar, Bangalore	Assistant. Surgeon cum Hon Lecturer in Medicine	1981-1989
5	Sri Jayadeva Institute of Cardiology	Assistant. Surgeon on Deputation	1989-1992
6	Sri Jayadeva Institute of Cardiology	Lecturer in Cardiology	1992-1997
7	Sri Jayadeva Institute of Cardiology	Assistant Professor of Paediatric Cardiology	1997 till 2006

8.	Sri Jayadeva Institute of Cardiology	Professor of Paediatric Cardiology	2006 till date
	Medical Society Membership	<ul style="list-style-type: none"> • Life member of Indian Medical association • Life member of Association of Physician of India • Life member of Cardiological Society of India • Life member of Cardiological Society of India, Karnataka Chapter. • Life member of Indian College of Cardiology • Life member of Indian Academy of Echocardiography • Life member of Indian Academy of Electrocardiography • Life member trustee of Medical Education & Research Trust • Life Member of Paediatric Cardiological Society • Member of American Society of Echocardiography 	
	Fellowships	<ul style="list-style-type: none"> • Fellow of Indian College of Cardiology in 1995 • Fellow of Indian Academy of Medical Specialities (F.I.A.M.S) in 1997 • Fellow of Indian Academy of Echocardiography (F.I.A.E) in 2002 • Fellow of Indian College of Physicians in 2003 • Fellow of Cardiological Society of India 2006 • Fellow of National Academy of Medical Sciences 2011 	

SPECIAL SERVICE TO THE PROFESSION / COMMUNITY

- a) **Delivered lecture in Kannada on ‘Effect of Globalization on Woman, Child and Health’ during the prestigious 72nd Kannada Sahithya Samelanna held at Bidar on 29.1.2006.**
- b) **Delivered lectures in Kannda at Science Forum for four times –2003, 2005, 2007, 2008, 2012**
- c) Interviewed in ‘Parichaya’ on Udaya TV as woman achiever on occasion of Woman’s Day 2005 and was introduced as “Prathamagala Saramaaleya Saradaarini” and ‘Chinnada Raani’ for getting many gold medals.
- d) Columnist for **Prajavani** newspaper from 2005-2008 and Vijaya Karnataka, Samyukta Karnataka, Hosa Diganta, Kamaveera, Taranga, Soundrya writing on social issues 2008
- e) ‘Water Quality and Health’, **keynote address** at the International Workshop on Integrated Water Resource Management (IWRM 2007), Bangalore on 5.2.2007.

- f) **'Jeevana Dhare'** first kannada book release on 13.1.2008
- g) Conducted free cardiac check up camps all over Karnataka organized by API / IMA / CSI / SJIC / MERT / Lions and Rotary Clubs
- h) AIR and TV talks for general public on various cardiology topics.
- i) Booklets printed in Kannada and English on Congenital Heart Disease
- j) Public lecturers in English and Kannada at different place in Karnataka.
(Total -450, International- 4)
- k) Organized World Health Day, 'Move for Health' 2002
- l) Organized successfully No Tobacco Day in 2004, 2005, 2005, 2006, 2007, 2008. **Presented 10,000 signatures against tobacco consumption to the Governor in 2004**
- m) 'Karuna Sindhu' Scheme to get donations for poor children with heart disease to undergo treatment.
- n) Successfully organized the World Heart Day 2007, 2008 as President of CSI, Bengaluru Chapter
- o) 'Jeevana Jyothi' Kannada book released in December 2010.
- p) CD of Kannada Rhymes(Kannada Kandamagalige Kavanagalu) released in December 2010.
- q) CD on devotional songs and on 'Akkamahadeviya Amara vachanagalu' released in December 2010.
- r) Anchored 'Ladies Doctor' on Udaya TV in March 2011 for improving the health awareness especially amongst women.
- s) On Panel in "Samakaleena Mahile" during Vishwa Kannada Sammelana March 2011 in Belagavi

Hobbies : Dancing, Singing, Oil Painting, Rangoli, gardening, writing columns in daily newspapers, books. Travelling and **Trekking- Maanasa Sarovar and Kailash Parvat Parikrama successfully done.** District level champion in Kho Kho and athletics **in Belagavi.**

Papers that won BEST PAPER AWARD at State and National level.

1. I.B. Vijayalakshmi Won best paper API award for "Low Blood Pressure Truth or Myth" at Bellary Conference in 1991.
2. R.Bhagirath, KG Kallur, Vijayalakshmi, ST Yavagal. Role of single Photon emission computed tomography in decision making in Coronary Artery Disease during annual conference of CSI state in 1998.

3. I.B. Vijayalakshmi, L. Sridhar, N. Chitra, , A.N. Prabhu Deva: Challenges of Closing Large PDA with Pulmonary Hypertension with Amplatzer Duct Occluder: Is Balloon Sizing Needed? during annual conference of CSI state in 2002.
4. I.B. Vijayalakshmi, U Ilayaraja, N Chitra, Rajasri, CN Manjunath, B Ramesh, R Bingi, S Shankar, B Kumar, ST Yavagal. “Balloon Valvuloplasty for Critical Aortic Stenosis: Initial Results and Mid-Term Follow-up” at 56th National CSI 2004 at Bangalore. **Best Poster paper award**
5. Dr.I.B.Vijayalakshmi, Dr. O.R.Vishnu Prabhu, Dr. N Chitra, Dr. R Rajasri, Dr. Anuradha, Dr. S.T.Yavagal. ‘Efficacy Echocardiographic criteria for diagnosis of carditis in Acute Rheumatic fever’ for Dr D.P Basu Award during 15th Asia Pacific Congress of Cardiology and 57th Annual conference of CSI at Mumbai on 3.12.1005.
6. Dr.I.B.Vijayalakshmi, Dr. Arunavalli, Dr. S.T.Yavagal. ‘Assessment of right ventricular function in Congenital Heart disease: Correlation between various echocardiographic indices’ for Dr D.P Basu Award during 15th Asia Pacific Congress of Cardiology and 57th Annual conference of CSI at Mumbai on 3.12.1005.
7. Dr I.B Vijayalakshmi, Dr Praveen, Dr Chitra, Dr Manjunath. Transcatheter closure of large PDA in infants less than 6ks at Annual Conference of the Karnataka Chapter of CSI at Belgaum in August 2010. **Won the first prize.**
8. Dr Jayashree, Dr IB Vijayalakshmi, Dr Manjunath – ADO II in non-ductal position. Won the best abstract prize at the National Interventional council meeting held at Kolkata in April 2013

PRESENTATIONS AT SCIENTIFIC MEETINGS - 130 papers (including 45 international)

ORGANIZATIONAL EXPERIENCE

1. As a trustee and Secretary of Medical education Research Trust of Karnataka, has conducted many CME, National Symposia and Workshops for Doctors.
2. Conducted live workshop in 1999, 2002 on Congenital heart disease with Children’s Heart Link, USA.
3. Worked as member of organizing committee of National Conference of API held in Bangalore in 1985,1998.
4. Worked as member of organizing committee of National CSI conference at Bangalore in 1996, 2002.
5. Chairman, Souvenir Committee for National Conference of Hypertension in 2001
6. Organising secretary for sports medicine conference during IMA’s Doctors day celebration in 1996.

7. Secretary IMA Academy of Medical Speciality, Bangalore chapter 96-97.
8. Hon. Joint Secretary CSI, Bangalore 1996-97
9. Vice chairman of IMA Academy of Medical specialities- 1997-98
10. Hon. Secretary CSI, Bangalore Chapter 1997-98
11. Chairman of IMAAMS 1998-99
12. Vice Chairman of the API Karnataka Chapter, 2001 –2002
- 13. Convenor of Sub-speciality Council for Congenital Heart Diseases** of CSI for the years 2002 – 2004, 2012. Proposed the National Policy for Congenital Heart disease .
- 14. Convenor of Sub-speciality Council for Rheumatic Heart Diseases** of CSI for the year 2013.
15. Secretary of Medical Education and Research Trust from 2003-2007.
16. President, **Cardiological Society of India**, Karnataka Chapter, 2004-05
17. Organising Convenor for Dr. K.S.Shadaksharappa National Symposium of Cardiology in 2003, 2004, 2005, 2006, 2007
18. Examiner for DNB in Cardiology and DNB in Pediatric Cardiology Fellowship, 2006, 2007
- 19. President of Indian Academy of Echocardiography, Bangalore Chapter, 2007-2008**
20. Organizing Secretary of SASAT 2006 held at Bangalore, October, 2006
21. Worked as member of organizing committee for National Conference of Echocardiography in 2006 at Bangalore .
- 22. President, Cardiological Society, Bangalore Chapter, 2007-2008**
23. Organizing convenor for Echo symposium on ‘Practical tips in Echocardiography’ on 25.5.2008 at Bangalore.
24. Organised the Silver Jubilee valedictory function of the CSI, Bangalore chapter with live beaming of the program on Doordarshan on 23.8.2008.
25. Governing council member of JSS Medical College.
26. Governing council member of PES University.
27. Organizing Secretary of WCCPC 2013 held at Suttur Mysore in September 2013.

Academic Guest lectures given: 420 (including 16 international)

Public health guest lectures given: 500 (including 5 international). > 100 TV shows and Radio talks.

Chief Guest at various forums in Hundreds of functions.

Publications of Dr Vijayalakshmi

MEDICAL BOOKS

- a) **“Step by step ECHO in Congenital Heart Disease”** 2006, Jaypee Brothers Medical publishers, New Delhi.
- b) Monogram on **‘Acute Rheumatic Fever and Chronic Rheumatic heart disease’** January 2011 by Jaypee brothers Medical publishers. Chief Editor.
- c) **Comprehensive approach to Congenital Heart diseases –2013** by Jaypee brothers Medical publishers. Chief Editor.
- d) **Cardiac catheterization and Imaging – 2015 by Jaypee** brothers Medical publishers. Editor.
- e) Health education books in local language kannada (nine)

CONTRIBUTION TO CHAPTERS IN BOOKS

1. Vijayalakshmi, 'Coronary Heart Disease in Indian Women - Change the Gender Bias', chapter in Coronary Artery Disease in South Asians: Epidemiology, Risk Factors and Prevention edited by Drs.Gundu HR Rao and Vijay V. Kakkar released during the SASAT (South Asian Society of Atherosclerosis and Thrombosis) conference held in Mumbai in December 2000.
2. I.B.Vijayalakshmi. 'Echo in Acute Rheumatic fever - Indian context'- chapter in book- Echocardiography: Current Trends. Volume I by Dr. P.C. Manoria. Published 2002.
3. I.B.Vijayalakshmi. 'Can Echocardiogram replace Cardiac Catheterization in decision making in Congenital Heart Disease? - Chapter in book- Echocardiography: Current Trends. Volume II - Dr. P.C. Manoria. Published 2003.
4. IB Vijayalakshmi,” Care of the children suffering from heart disease 2003
5. I.B.Vijayalakshmi. 'Care of the Children suffering from Heart disease' - Chapter in Book, “Guide to Prevention of Heart disease and Healthy Life” edited by Dr. Ram Kumar, Dr.Meenal Kumar. Published by Deep and Deep Publications Pvt. Ltd. 2004.
6. I.B.Vijayalakshmi 'Echocardiogram can replace catheterisation in the management of Congenital Heart Disease' Medicine Update 2005 Vol 15 Chapter 25: 124-128.
7. I.B.Vijayalakshmi 'Importance of early detection of subaortic membrane' Medicine Update 2005 Vol 15 Chapter 25: 129-131.
8. I.B.Vijayalakshmi 'Device Closure of unusual shunts' Cardiology Update 2005 released during the 15th Asia Pacific Congress of Cardiology and 57th Annual conference of CSI at Mumbai in December 2005.
9. IB Vijayalakshmi, M Satpathy. Bedside Diagnosis and classification of Congenital Heart Disease. Clinical diagnosis of Congenital Heart Disease. Editor- M Satpathy. Jaypee Brothers Medical Publishers. 2008.
10. Rheumatic fever and rheumatic heart disease : Preventive strategies in Heart Protection Book eds Dr H K Chopra, New Delhi 2011.

Contributed 10 chapters in Acute Rheumatic fever and Chronic rheumatic heart disease. Editor. I B Vijayalakshmi. Jaypee Brothers Medical Publishers, 2011.

11. I B Vijayalakshmi. Lessons Learnt from History of Rheumatic Heart Diseases.
12. I B Vijayalakshmi, Usha Anand. Etiopathogenesis and Management of Streptococcal Infection.
13. I B Vijayalakshmi, Chitra Narasimhan. Etiopathogenesis, Clinical Manifestations and Diagnosis of Acute Rheumatic Fever.
14. I B Vijayalakshmi. Role of Echocardiography in Diagnosis of Carditis in Acute Rheumatic Fever.
15. I B Vijayalakshmi, Chitra Narasimhan. Role of Echocardiography in Rheumatic Heart Disease.
16. I B Vijayalakshmi. Consensus and Controversies in the Management of Acute Rheumatic Fever.
17. I B Vijayalakshmi. Prevention and Vaccine for Rheumatic Fever: How Far are We?
18. I B Vijayalakshmi, Asha Moorthy. Natural History of Rheumatic Fever and Rheumatic Heart Disease.
19. Ramesh Arora, I B Vijayalakshmi. Transcatheter Treatment of Rheumatic Mitral Stenosis in Pediatric Age Group.
20. I B Vijayalakshmi Rheumatic Fever, Rheumatic Heart Disease Registry and Control Program.
21. 'History of rheumatic fever chapter in 'History of Cardiology' by Dr H K Chopra. Jaypee Brothers Medical Publishers 2012.

Contributed 16 chapters in Comprehensive approach to Congenital Heart diseases – Eds. I B Vijayalakshmi, P S Rao, Reema Chugh. Jaypee Brothers Medical Publishers. 2013.

22. Chitra Narasimhan, Vijayalakshmi IB. Fetal Circulation.
23. Prabhat Kumar, Vijayalakshmi IB. Classification of Cardiovascular Anomalies and their Terminologies.
24. Vijayalakshmi IB, Satpathy M. Bedside Diagnosis of Acyanotic Congenital Heart Diseases.
25. Madhav Hegde, Vijayalakshmi IB. Role of Radiography in Congenital Heart Diseases.
26. Jayashree Kharge, Vijayalakshmi IB. Anomalies of Systemic Veins.
27. Vijayalakshmi IB, Chitra Narasimhan, Prasanna Simha Mohan Rao. Ventricular Septal Defects.
28. Ramesh Arora, Vijayalakshmi IB. Patent Ductus Arteriosus.
29. Vijayalakshmi IB, Praveen Jayan, Satish Govindaiah. Aortopulmonary Window.
30. Vijayalakshmi IB, Chitra Narasimhan. Aortico-Cameral Tunnels.
31. Vijayalakshmi IB, Vimala J. Left Ventricular Outflow Tract Obstructions.
32. Vijayalakshmi IB, Prasanna Simha Mohan Rao. Interruption of Aortic Arch.
33. Suresh Kumar, Vijayalakshmi IB, Bhushan Chavan. Tetralogy of Fallot.
34. Vijayalakshmi IB. Pulmonary Stenosis with Interatrial Communication.
35. Vimala J, IB Vijayalakshmi, Prasanna Simha Mohan Rao. Double Outlet Right Ventricle.
36. Vijayalakshmi IB. Non-compaction of Ventricles.

37. BhanuDuggal, Vijayalakshmi IB. Cardiac and Extracardiac Masses.
38. IB Vijayalakshmi. Lessons learnt from history of rheumatic heart disease. Textbook of Cardiology: A clinical and historical perspective. Eds: HK Chopra, Nanda N. Jaypee Brothers Medical Publishers. 2013.
39. Vijayalakshmi IB. Echocardiography in acute rheumatic fever and chronic rheumatic heart disease. Eds. Nanda N. Comprehensive text book of echocardiography- Jaypee Brothers Medical Publishers. 2014.
40. Vijayalakshmi IB, Chitra N. Valvular heart disease in women. Eds. Nanda N, Keser N. Heart Disease in women. Jaypee Brothers Medical Publishers. 2015.
Contributed 5 chapters in Cardiac Catheterization and Imaging (From Pediatrics to Geriatrics)– Eds.I B Vijayalakshmi, Jaypee Brothers Medical Publishers. 2015
41. Chitra Narasimhan, IB Vijayalakshmi. History of Transcatheter Interventions in Adult Cardiology
42. IB Vijayalakshmi, Chitra Narasimhan. Balloon Valvuloplasty for Aortic Stenosis.
43. McGovern E, Walsh K, IB Vijayalakshmi, O’Callaghan. . Device Closure of Ventricular Septal Defect
44. IB Vijayalakshmi. Interventions in Patent Ductus Arteriosus
45. K Sivakumar, IB Vijayalakshmi. Closure of unusual defects: Tunnels and Leaks
46. Vijayalakshmi IB. Ventricular septal defect. Textbook of Pediatrics for Postgraduates Eds. Piyush Gupta, PSN Menon, Siddarth Ramji, Rakesh Lodha.
47. Vijayalakshmi IB Echocardiography: A boon for ante mortem diagnosis of intracardiac masses. Eds. PC Manoria. Post Graduate Medicine-2014. (in print)
48. Vijayalakshmi IB, Nagamani AC. STEMI IN Rheumatic heart disease. Eds: HK Chopra. STEMI. Jaypee Brothers Medical Publishers. 2015.

PUBLICATIONS IN INTERNATIONAL MEDICAL JOURNALS

1. Vijayalakshmi IB, Chitra N, Prabhu Deva AN. Use of an Amplatzer duct occluder for closing an aortico-left ventricular tunnel in a case of noncompaction of the left ventricle. *PediatrCardiol.* 2004 Jan-Feb;25(1):77-9.
2. Vijayalakshmi IB, Yavagal ST, Prabhudev N. Role of echocardiography in assessing the mechanism and effect of ramipril on functional mitral regurgitation in dilated cardiomyopathy. *Echocardiography.* 2005 Apr;22(4):289-95.
3. Vijayalakshmi IB, Chitra N, Rajasri R, Prabhudeva AN. Amplatzer angled duct occluder for closure of patent ductus arteriosus larger than the aorta in an infant. *PediatrCardiol.* 2005 Jul-Aug;26(4):480-3.
4. Vijayalakshmi IB, Mithravinda J, Deva AN. The role of echocardiography in diagnosing carditis in the setting of acute rheumatic fever. *Cardiol Young.* 2005 Dec;15(6):583-8.
5. Vijayalakshmi IB, Chitra N, Rajasri R, Vasudevan K. Initial clinical experience in transcatheter closure of large patent arterial ducts in infants using the modified and angled Amplatzer duct occluder. *Cardiol Young.* 2006 Aug;16(4):378-84.
6. Vijayalakshmi IB, Vishnuprabhu RO, Chitra N, Rajasri R, Anuradha TV. The efficacy of echocardiographic criterions for the diagnosis of carditis in acute rheumatic fever. *Cardiol Young.* 2008 Dec;18(6):586-92.
7. Vijayalakshmi IB, Devananda NS, Chitra N. A patient with aneurysms of both aortic coronary sinuses of Valsalva obstructing both ventricular outflow tracts. *Cardiol Young.* 2009 Sep;19(5):537-9.

8. Jayan JP, Vijayalakshmi IB, Narasimhan C. A rare anomaly: 'hemitruncus'. *Heart* 2011. Jun;97(12):1027.
9. Reményi B, Wilson N, Steer A, Ferreira B, Kado J, Kumar K, Lawrenson J, Maguire G, Marijon E, Mirabel M, Mocumbi AO, Mota C, Paar J, Saxena A, Scheel J, Stirling J, Viali S, Balekundri VI, Wheaton G, Zühlke L, Carapetis J. World Heart Federation criteria for echocardiographic diagnosis of rheumatic heart disease--an evidence-based guideline. *Nat Rev Cardiol*. 2012 Feb 28;9(5):297-309.
10. Vijayalakshmi IB, Chitra N, Praveen J, Prasanna SR. Challenges in device closure of a large patent ductus arteriosus in infants weighing less than 6 kg. *J Interv Cardiol*. 2013 Feb;26(1):69-76.
11. Singh B, Kariyappa M, Vijayalakshmi IB, Nanjappa MC. Holt-Oram syndrome associated with double outlet right ventricle: A rare association. *Ann Pediatr Cardiol*. 2013 Jan;6(1):90-2.
12. Vijayalakshmi IB, Narasimhan C, Agarwal A. Closure of Aorto-Right ventricular tunnel with Amplatzer Duct Occluder II. *J Invasive Cardiol*. 2013 Apr;25(4):E75-7.
13. Vijayalakshmi IB, Narasimhan C, Agarwal A. Transcatheter closure of left coronary cameral fistula With Amplatzer Duct Occluder II. *J Invasive Cardiol*. 2013;25(5):265-267.
14. Vijayalakshmi IB, Agrawal N, Narasimhan C, Kavya M, Bagi V, Manjunath CN. Percutaneous closure of pseudoaneurysm of common iliac artery with Amplatzer duct occluder II. *Cardiovasc Interv Ther*. 2014 Jan;29(1):76-81.
15. Vijayalakshmi IB, Agrawal N, Mallikarjun K, Manjunath CN. The retrieval of the diagnostic catheter which broke and embolised twice. *BMJ Case Rep*. 2013 Jul 24;2013.
16. Vijayalakshmi IB, Agrawal N, Mallikarjun K, Manjunath CN 'Floating' left atrial appendage in an infant with chylopericardium. *BMJ Case Rep*. 2013 Aug 23;2013
17. Vijayalakshmi IB, Narasimhan C, Singh B, Manjunath CN. Treatment of congenital non-ductal shunt lesions with Amplatzer Duct occluder II. *Catheter Cardiovasc Interv*. 2013 Oct 15.
18. Singla V, **Vijayalakshmi** IB, Singh B, Narsimhan C. Jarcho-Levin syndrome: a rare syndrome presented with asymptomatic cardiac murmur. *BMJ Case Rep*. 2014 Feb 13;2014.
19. Vijayalakshmi IB, Narasimhan C, Mahapatra A, Manjunath CN. Echocardiography in the diagnosis of apical non-compaction associated with congenital heart diseases. *J Echocardiogr*. 2014 Mar; 12 (1); 31-39.
20. Vijayalakshmi IB, Setty HS, Narasimhan C. Unusual cases of right-sided and left-sided May-Thurner syndrome. *Cardiol Young*. 2014 Jul 10:1-3.
21. Vijayalakshmi IB, Setty N, Narasimhan C, Singla V, Manjunath CN. Percutaneous device closure of patent ductus arteriosus with pulmonary artery hypertension: long-term results. *J Interv Cardiol*. 2014 Dec;27(6):563-9.
22. Natraj Setty HS, Vijayalakshmi IB, Narasimhan C, Manjunath CN. Purulent pericarditis with quadruple valve endocarditis. *Am J Case Rep*. 2015 Apr 23;16:236-9.
23. Vijayalakshmi B, Kariyappa M, Agrawal N, Narasimhan C, Tanveer SA, Manjunath CN. Renal artery coil embolization of a non-functional kidney: A novel method to treat resistant hypertension in paediatric patients. *Journal of Indian College of Cardiology* 2015; 5 (3): 231-234.
24. Setty HSS, Vijayalakshmi IB, Narasimhan C, Manjunath CN. Aortopulmonary Window in Association with Subpulmonic Ventricular Septal Defect and Non Compaction of Left Ventricle. *Journal of Cardiovascular Disease Research*, 2015; 6(4):197-199

25. Vijayalakshmi IB, Govindappa S, Narasimhan C, Manjunath CN. Multiple intracardiac tumors secondary to non-Hodgkin lymphoma. *J Echocardiogr.* 2015 Sep;13(3):113-5.
26. Vijayalakshmi IB, Natraj Setty HS, Chitra N, Manjunath CN. Amplatzer duct occluder II for closure of congenital Gerbode defects. *Catheter Cardiovasc Interv.* 2015 Nov 15;86(6):1057-62.
27. Vijayalakshmi IB. Evaluation of Left to Right Shunts by the Pediatrician: How to Follow, When to Refer for Intervention? *Indian J Pediatr.* 2015 Nov;82(11):1027-32.

PUBLICATIONS IN NATIONAL MEDICAL JOURNALS

1. Vijayalakshmi, A.S. ChandrashekharaRao, S.T. Yavagal. Frequency of various Congenital Heart Diseases: Analysis of 3790 Consecutive Catheterised patients - *Indian Heart Journal* 1995;47:125-128.
2. Vijayalakshmi. 'Newer and Novel Methods of treating Cardiovascular Diseases. 2001. Association of Physicians of India. Online.
3. Vijayalakshmi. 'ASD closure by Amplatzer Device' in "Images" in *Karnataka Journal of Medical Sciences* Oct-Dec 2001.
4. Vijayalakshmi. Recent Advances in Management in of Non-specific Aorto-arteritis. *Indian J Pediatr.* 2002 Jun;69(6):523-6.
5. Vijayalakshmi I.B. 'Present Scenario of Device closure for Congenital Heart Diseases'. *J Indian Med Assoc.* 2003 Feb;101(2):86-8. Review.
6. I.B. Vijayalakshmi. 'Role of Echocardiography in Rarest Congenital Heart Disease' in *Journal of Indian Academy of Echocardiography* Sep-Dec 2003: Vol. 7 No. 4: 509-512.
7. I.B. Vijayalakshmi 'Importance of early detection of subaortic membrane' *Journal of Indian Academy of Echocardiography* Nov 2004-Feb 2005: Vol. 7, No.5 : 625-627.

Citation Analysis of six best Research papers by Dr Vijayalakshmi

1. Vijayalakshmi S, A.S. ChandrashekharaRao, S.T. Yavagal. Frequency of various Congenital Heart Diseases: Analysis of 3790 Consecutive Catheterised patients - *Indian Heart Journal* 1995;47:125-128.
2. Vijayalakshmi IB, Chitra N, Prabhu Deva AN. Use of an Amplatzer duct occluder for closing an aortico-left ventricular tunnel in a case of noncompaction of the left ventricle. *PediatrCardiol.* 2004 Jan-Feb;25(1):77-9.
3. Vijayalakshmi IB, Mithravinda J, Deva AN. The role of echocardiography in diagnosing carditis in the setting of acute rheumatic fever. *Cardiol Young.* 2005 Dec;15(6):583-8.
 K. Initial clinical experience in transcatheter closure of large patent arterial ducts in infants using the modified and angled Amplatzler duct occluder. *Cardiol Young.* 2006 Aug;16(4):378-84.
4. Vijayalakshmi IB, Yavagal ST, Prabhudev N. Role of echocardiography in assessing the mechanism and effect of ramipril on functional mitral regurgitation in dilated cardiomyopathy. *Echocardiography.* 2005 Apr;22(4):289-95.
5. Vijayalakshmi IB, Chitra N, Rajasri R, Vasudevan K. Initial clinical experience in transcatheter closure of large patent arterial ducts in infants using the modified and angled Amplatzler duct occluder. *Cardiol Young.* 2006 Aug;16(4):378-84.
6. Vijayalakshmi IB, Vishnuprabhu RO, Chitra N, Rajasri R, Anuradha TV. The efficacy of echocardiographic criteria for the diagnosis of carditis in acute rheumatic fever. *Cardiol Young.* 2008 Dec;18(6):586-92.

TOTAL NUMBER OF PAPERS ANALYSED	6
CITED PAPERS	6
TOTAL CITATIONS	100
AVERAGE CITATIONS	16.7
MAXIMUM CITATIONS RECEIVED BY A PAPER	26
SELF CITATION	7

Other Publications:

1. Vijayalakshmi, S.T. Yavagal, A.S. Chandrashekhara Rao. Percutaneous Balloon Angioplasty in the management of Hypertension in Aortic obstruction. K.M.J 1993 Vol.63:3:23-25.
2. Vijayalakshmi, S.T. Yavagal, A.S. Chandrashekhara Rao. Percutaneous Balloon Pulmonary Valvuloplasty for Pulmonary stenosis. K.M.J. 1993.
3. Vijayalakshmi, A.S. Chandrashekhara Rao. Low blood pressure, truth or myth K.M.J. 1994 Vol. 64: 2:14-18.
4. Vijayalakshmi. 'Strange but True' - Souvenir South Zone Conference of API & CSI - 1996.
5. Vijayalakshmi. 'Quest for Excellence'. Souvenir 48th Annual conference of Cardiological Society of India 1996.
6. Vijayalakshmi. 'Unsung Heroes'- Souvenir of II International Symposium of South Asian Society of atherosclerosis and thrombosis 1996 & Heart in English & Kannada.
7. Booklet on Tobacco & Heart Disease printed by Cardiological Society of India Bangalore Chapter 1997.
8. Booklets for parents printed in Kannada and English on Congenital Heart disease.
9. Vijayalakshmi. 'Interventional Paediatric Cardiology- Current Scenario' in the booklet released on inauguration of Child Heart Care Centre, Sri Jayadeva Institute of Cardiology. 1998.
10. Vijayalakshmi. Transcatheter coil closure of PDA in Jayadeva Pulse, Jan 1999.
11. Vijayalakshmi. 'Hypertension- Yesterday and Today' in Souvenir released for National Conference of Hypertension, Oct 2001.
12. Vijayalakshmi. 'Challenges of closing large PDA without surgery: by Amplatzer Device' in Jayadeva Pulse Nov 2001.
13. Proceedings of Conference of National Conference of Hypertension held in Bangalore 2001. Multiple author, copies given in conference.
14. Booklet on Congenital Heart Disease in Kannada released in February 2002.
15. Vijayalakshmi. 'Heart Attack' in booklet released for World Health Day on April 7th 2002.
16. Vijayalakshmi - 'Ill effects of Tobacco on cardiovascular system' article in Kannada in the booklet released on occasion of No Tobacco Day 31st May 2004.
17. I.B.Vijayalakshmi - 'Tobacco and Cardiovascular Diseases' in official publication of IUHPE-SEARB Health, Promotion and education in South East Asia, October 2004.
18. "Device closure in Congenital Heart Disease" in October-December 2005 issue of PEDISCAN. official journal of IAP Bangalore BPS. 'Evidence based Protocol for endocarditis' in July 2006 issue of PEDISCAN.
19. "Practice of Pediatric Cardiology: Past, Present and Future" in Hridmilan, Souvenir of 4th Annual Conference of CSI, Karnataka, held at Mysore in September 2006.

20. "Importance of water quality in preventing diseases and health" in souvenir released during EAB seminar at Bangalore on 9.6.2007.
21. "Seeds of coronary artery disease" in July 2007 issue of PEDISCAN
22. "Pediatric Cardiology – Past, Present and Future" in souvenir released on occasion of silver jubilee function of CSI, Bangalore Chapter in August 2008.
23. Rheumatic fever a neglected giant in Cardiology update released in CSI annual conference in December 2012.
24. **Karnatakada Veera Vaniteyaru' article is published in the Kannada text book for 10th standard. 2014**
25. Vijayalakshmi IB. Echocardiography in Acute Rheumatic Fever and Chronic Rheumatic Heart Disease. Cardiology Update 2014.
26. Vijayalakshmi IB. " Rheumatic Fever in India: Future directions "-2015. Cardiology Update 2015.

CURRICULUM VITAE

PERSONAL DETAILS

Name **Dr. Ashwin Prabhu**

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132/6, 24th Main, 6th phase
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Email Address prabhu.ash@gmail.com

Date of Birth 14-08-1977

Marital Status Married

Nationality Indian

Place of Birth Mangalore, India

EDUCATION

School 1982-1984 Demonstration School, Mysore, India
1984-85 to 1990-91 National English School, Bangalore, India
1991-92 to 1992-93 Indian High School, Dubai, U.A.E

University 1993-94 to 1994-95 St. Aloysius College, Mangalore, India

Clinical School 1995-96 to 2001 **Government Dental College,**
Bangalore, India

2002-2005 **Bapuji Dental College & Hospital,**
Davangere, India

POST GRADUATE QUALIFICATIONS

2005 Master of Dental Surgery (M.D.S) in Periodontics

ACADEMIC APPOINTMENTS & EXPERIENCE

Senior Lecturer, Dept. of Periodontics , Dayananda Sagar College of Dental Sciences, Bangalore. (Dec 2005 – Dec 2009 – 4 Years)

Reader, Dept. of Periodontics , K.L.E Society’s Institute of Dental Sciences, Bangalore. (Dec. 2009- Present day- 5 Years 6 months)

TOTAL TEACHING EXPERIENCE

10 years 3 months as of date.

COMPLETED RESEARCH

“A Morphologic and Histologic Comparison Of Gingival Changes Induced By Cyclosporin And Tacrolimus In Rats - An Experimental Study.”

(Academic dissertation submitted to Rajiv Gandhi University of Health Sciences, Bangalore as partial fulfilment of M.D.S (Periodontics) course, 2005.)

Dissertation Guide for “Quantitative Estimation of Salivary & GCF MMP-8 levels in Chronic Periodontitis Pre & Post Non Surgical Therapy- A Clinico-Biochemical study” submitted to the Rajiv Gandhi University of Health Sciences in 2013.

Dissertation Co-Guide for “Comparative Evaluation Of Gingival Tissue Response And Tensile Strength Of Suture Materials : A Histomorphometric And In Vitro Study.”(2014)

CURRENT/ONGOING RESEARCH PROJECTS

Dissertation Co-Guide for “Comparative Evaluation Of Regenerative Potential Of Auto Tooth Bone Graft And Alloplastic Nanocrystalline Hydroxyapatite In Management Of Periodontal Intraosseous Defects - A Clinico-Radiographic Study. (2015)

Co-investigator- Assessment of Streptococcus Mutans in plaque and saliva of healthy, gingivitis and chronic periodontitis- A clinic-microbiological study (2015)

ACADEMIC ACHIEVEMENTS

Recipient of the **Prof. J.E. Venson Gold medal** awarded by the Bangalore University for having secured the highest marks in final year B.D.S degree examination held in September 1999.

Recipient of the **Dr. S. Channabasappa Memorial Gold medal** awarded by the Bangalore University for having secured the highest marks in B.D.S (first to final year) degree examination held in September 1999.

PUBLICATIONS:

TEXTBOOK:

Author of 2 chapters in the “*Comprehensive textbook of periodontology with Color Atlas, 3rd edition*” on topics “Computers in dentistry” and “Ageing and the periodontium.” by AIPD publishers released in March, 2015.

NATIONAL JOURNALS:

Periodontal regeneration-fantasizing the future. Indian J Dent Res. 2003 Oct-Dec;14(4):246-53. PMID: 15328993

INTERNATIONAL JOURNALS:

A morphologic comparison of gingival changes influenced by Cyclosporin and tacrolimus in rats: an experimental study. J Periodontol. 2006 Feb;77(2):265-70. PMID: 16460253

Quantitative Digital Subtraction Radiography (DSR) as an approach for evaluating crestal alveolar bone density changes around teeth following orthodontic tooth movement. Int. Journal of Clinical Dental Science, Nov. 2011, 2(4):94-100.

Piezosurgery in Periodontics and Implantology: The Future Tool for Traditional Procedures? Research & Reviews: A Journal of Dentistry Volume 4, Issue2, (2013) 15-22.

Invited Guest Editorial : mHealth the emerging sub-segment of eHealth. The Journal of Contemporary Dental Practice, May-Jun 2013; 14(3)i.

Plasma Cell Gingivitis- An unusual presentation (Accepted for publication at International Journal of Clinical Dental Science, 2015)

PRESENTATIONS AND OTHER ENGAGEMENTS:

Guest speaker at “Workshop in information technology in medicare” held by the Dept. of Information Science, Dayanand Sagar College of Engineering, Bangalore. 10 May 2006.

Panelist in the ‘Research and Dissertation’ group at the National Teachers’ Convention in Periodontics, Rajiv Gandhi University of Health Sciences, Bangalore . June 2-3 , 2006.

Chair Person- PG Scientific paper presentation, 10th Indian Society Of Periodontology, PG Workshop, 24th & 25th June 2011, Chennai.

Guest Speaker at Symposium on “**ORAL SYSTEMIC HEALTH**” at K.L.E Society’s Institute of Dental Sciences, conducted by Colgate India Ltd. In Bangalore on 19.07.2012.

Organizing Secretary of symposium on stem cells-applications in dentistry and Periodontal regeneration held on 23rd December 2013 in Bangalore.

Panelist at Viva Voce panel discussion @ “Periopanorama” held in MR Ambedkar Dental College, Bangalore on 15-02-2014.

Organizer at “Periocharcha 2015” – An intercollegiate post graduate Scientific debate to be held on 1st Aug 2015.

BIO-DATA

PERSONAL DETAILS

Name: Dr. Sudhir R Patil

Date of birth: 21/09/1963

Address: Flat no S-3, Block B, No 36-39,
Reliance mansions
Hariram Aildas Layout, Vijaynagar,
Bangalore-40

Telephone: Residence: 080-23207676
Mobile: 9845560110

E-mail: zonaperiosrp@rediffmail.com

Present designation Professor & HOD, Department of Periodontics & Vice-Principal,
K.L.E Society's Institute of Dental Sciences, Bangalore

Area of Special Interest in Preventive Periodontics, **Regenerative Periodontics**, Microbiology
Periodontics of Periodontal diseases, Halitosis, Lasers , **Perio-Esthetics**,
Periodontal research , Medical ethics and Law., **Medical teaching**
& learning methodology

EDUCATIONAL QUALIFICATION

QUALIFICATION	INSTITUTE & UNIVERSITY	MONTH & YEAR OF PASSING
Bachelor Of Dental Surgery (BDS)	Government Dental college, Bangalore Bangalore university	August 1988
Master Of Dental Surgery- Periodontics (MDS)	Government Dental college, Bangalore Bangalore university	February 1992

***Certificate course in Pyramid Spiritual Sciences from PSS Academy, Bangalore**

ACADEMIC HIGHLIGHTS

Teaching Experience:

- Total of over 23 years of teaching experience at reputed Dental institutes post MDS and around 17 years of Post graduate teaching experience and guide for over 20 students.
- Professor and Head of Department of Periodontics for 8 years and as Principal for 1 year.
- Actively involved in academic and scientific activities related to speciality of Periodontics.
- Chairperson/Judge for scientific sessions at National Conferences and Conventions.

Papers Presented: At National Conferences and various other forums

Publications: Total =27 (18 International + 9 National)

Guest Lectures : 15

EXAMINATION/INSPECTION RELATED EXPERIENCE

Examinerships

- UG and PG Examinership - RGUHS, Bangalore, K.L.E University, Belgaum, Manipal University, Manipal, M.G.R University, Chennai, NTR university, Andhra Pradesh , MUHS ,Nashik

Inspections

- Local Inspection committee (LIC), Rajiv Gandhi University of Health Sciences, Bangalore (RGUHS)
- Dental Council Of India (DCI)

MEMBERSHIPS

- Life member- Indian Society Of Periodontology (ISP); Bangalore academy of Periodontology (BAP); Indian Dental Association (IDA)
- Former EC member/ Editor, GDCRI Alumni Association..
- EC member/Internal Auditor , GDCRI Alumni Association**
- Chairperson, Institutional Ethics Committee (IEC), KIDS, Bengaluru
- Editorial Board Member – World Journal of Dentistry, KLE Dental Journal
- Reviewer for The Journal of Indian Society of Periodontology, JICD, IJDR
- Founder Trustee/Director-Pro-Know S3 Academy , Pyramid Spiritual Sciences Academy (PSSA), Bangalore Academy Of Periodontology (BAP)**
- Life member- Art Of living (AOL), Pyramid Spiritual Society Movement (PSSM)

HOBBIES

- Creative and scientific literature ; Yoga and meditation, Music & poetry

Curriculum vitae

Name : **DR. SANDYA DEVI S. PATIL**

Designation: Professor & Head
Department of Pedodontics and
Preventive Dentistry

EXPERIENCE DETAILS:

Designation	Duration	Institution
Asst. Prof	08-04-1996 to 30-09-1996 5 months 22 days	K.L.E. S. Institute of Dental Sciences. Belgaum
Asst. Prof	01-10-1996 to 09-09-1999 2 years 11 months 9 days	K.L.E. S. Institute of Dental Sciences. Bangalore
Reader	15-09-1999 to 04-05-2002 2years 7 months 18 days	P.M.N.M. Dental College and Hospital. Bagalkot
Asso. Professor	05-05-2002 to 07-04-2004 1 year 11 months 2 days	K.L.E. S. Institute of Dental Sciences. Bangalore
Professor	08-04-2004 to 14-12-2005 1 year 8 months 7 days	K.L.E. S. Institute of Dental Sciences. Bangalore
Professor	17-12-2005 to 14-04-2006	P.M.N.M. Dental College and Hospital. Bagalkot
Professor & Head	15-04-2006 to 30-6-2008 2 year 6 months 17 days	P.M.N.M. Dental College and Hospital. Bagalkot
Professor	01-07-2008 to 3-11-2009 1 year 4 months	The Oxford dental college Bangalore.
Professor & Head	4-11-2009 –till date	K.L.E. S. Institute of Dental Sciences. Bangalore

PUBLICATIONS:

1. Talon's cusp. Macrodonia, abbarant tooth marphology in female siblings with *Seip Berardinelli* syndrome - A case report . J. Oral Surg. Oral Med. Oral Path. Oral Radio and Endo. 2008 ; 108 : E 41-47
2. Gastroesophageal Reflux Disease Induced Dental Erosion, In focus, Pedodontics update 2008 ; vol.1, issue -5 ; 4-6
3. Pre – eruptive Intracoronal resorption of Dentine. In focus Pedodontics update 2008 ; vol .1, Issue -5 ; 13-14

4. Maxillary Prosthesis Rehabilitation following Hemi- Maxillectomy. Indian Dentist. 2007
5. Prevalence of developmental anomalies altering the number of teeth among school going children in Bagalkot city. RUJODS, Ranchi University 2012;1(1):40-49.
6. Oral lichen planus in childhood. K.L.E.S Dental Journal ,Vol-1, April- Sep. 2012
7. Sequelae of maxillofacial trauma on permanent successor – A cone beam computed tomography assisted diagnosis. KLE Health Sciences Journal, July- August 2012.
8. Oral health coalition: Knowledge, attitude, practice behavior among Gynecologists and dental practitioners. Journal of International Oral Health(2013), No1, Vol.5, (ISSN 2278-7372)
9. Full mouth rehabilitation of child with Ectodermal Dysplasia- A case report. Journal of dental peers, 2013;1(1)27-34
10. Ascorbic acid deficiency: A case report. Journal of Dentistry for Children 2011,78(2):115-119.
11. A KAP survey on Prenatal network of maternal and pediatric dentists on oral health care during Pregnancy in Bangalore city . Karnataka State Dental Journal 2014;1(1): 9-15.
12. Chemo-Mechanical caries removal technology – dentistry at ease. Indian Dentist Research and Review. November 2014;22-27.
13. A KAP survey on prenatal network of maternal and pediatric dentists on oral health care during pregnancy in Bangalore city. KSDC Journal – 2014;1(1)9-15.
14. Sparring misery of dentist's drill by carie care – A chemomechanical caries removal system. Guident 2014;34-36.

ACADEMIC ACHIEVEMENTS:

1. Chairing the Scientific session in 33rd ISPPD conference at Mangalore from 4th to 6th Nov'2011.
2. Delivered guest lecture on “Concepts of Pulp Therapy in Primary teeth in CDE on Dynamics of Pulp at Rajrajeshwari dental college on 8th april, 2014.
3. Chairing the Scientific session in 36th National ISPPD conference at Lucknow from 14th to 16th October, 2014.
4. Chairperson for the guest lecture delivered by Dr. Nikhil Marwah at 12th ISPPD National post graduate convention at Tumkur from 26th to 28th February 2015.
5. Delivered guest lecture “ Unraveling the unspoken - Communicating with differently disabled children at PEDO ART, 37th National ISPPD conference , Raipur on 8th October, 2015.
6. Chairing the Scientific session in PEDO ART, 37th National ISPPD conference , Raipur from 8th 10th October, 2015.

EPIDEMIOLOGICAL STUDIES CONDUCTED:

1. The state of infant oral health care Knowledge and awareness in Health care professionals of Bagalkot city (2007).
2. Prevalence of tobacco consumption among school going children of Bagalkot city(2007).

3. Tooth avulsion : Ignorance Vs Awareness in parents , Teachers & General practitioners of Bagalkot city (2007).

CONFERENCES & CDE PROGRAMMES ATTENDED

1. Clinical dental photography – hand on course, K.L.E. institute of Dental Sciences, Belgaum (1996)
2. Basic computer course and application on dental clinic management, computer education. (2000)
3. National level workshop on teacher training program by Dr. Chandrashekhar Nair, Organized by IOP and IDA Bagalkot. (Jun 2000)
4. Course on basic life support and CPR. (2004)
5. Training in Personality and development and human resource development courses like Art of living and SMET by Vivekananda Yoga Kendra .
6. CDE Program on “Chemical control of supra and subgingival plaque” by Prof Martin Addy at Hotel Grand Magrath , organized by IDA, Bangalore branch. 21-3 2010
7. P.G. orientation programme on 2 nd July 2010.
8. CDE Program on 13th Aug, 2010 Current concepts & recent advances in fixed Prosthodontics
9. CDE Program on 18th Aug, 2010 at KLE Society’s Institute of Dental Sciences, Bangalore “IDA – Colgate Academia Program” History & Facts.
10. CDE Program on 16th Sep, 2010 at KLE Society’s Institute of Dental Sciences, Bangalore “Pain management in Dentistry”.
11. CDE Program on 29th Sep, 2010 at KLE Society’s Institute of Dental Sciences, Bangalore Special care Dentistry - A Professional challenge, Challenges in Diagnosis (organized by Department of Pedodontics and Preventive Dentistry).
12. CDE Program on 8th Oct, 2010 at KLE Society’s Institute of Dental Sciences, Bangalore “Myth Busters - Academy of Conservative Dentistry & Endodontics.
13. Preconference Course on “ Use of Problem based learning in dental education” by Dr. Nadeem Kareem Bux on 27th-30th Oct, 2010.
14. 35th National Conference of Periodontics at Bangalore on 27th -30th Oct,2010.
15. CDE Program on 29th Nov, 2010 at KLE Society’s Institute of Dental Sciences, Bangalore “Infection Control Concepts “ In association with IAGD by Dr. Raghunath Puttaiah.
16. CDE Program on 11th Mar,2011 at KLE Society’s Institute of Dental Sciences, Bangalore on “All Ceramics” by Prof .Dr.Jean Francois Roulet in association Dept of Prosthodontics,Conservative dentistry & Ivoclar Vivadent.
17. “Competence in composites” by Dr.Jean Francois Roulet & Dr.Markus Lenhard at ITC Windsor in association with Ivoclar Vivadent on 12th Mar 2011.
18. CDE Program on : Lasers in Dental Practice organized at VS Dental College in association with IDA, Bangalore Branch.
19. Consultative workshop on restructuring of BDS regulation ,Rajiv Gandhi university of Health sciences 06-06-2011.

20. CDE Program on 10th June, 2011 at KLE Society's Institute of Dental Sciences, Bangalore on "Complete guide on complete dentures" in association with IDA & Bangalore prosthodontic forum.
21. CDE Program on 6th July 2011 at KLE Society's Institute of Dental Sciences, Bangalore on "Conscious sedation & career opportunities for dental graduates" organized by the Department of Periodontics & Department of Pedodontics.
22. CDE Program on "Dentin Hypersensitivity" hosted by Dept of Conservative Dentistry, K.L.E.Society's Institute of Dental Sciences & Hospital ,Bengaluru on 28/7/11
23. CDE Program on Pediatric Endodontics: The rotary revolution held at The Oxford Dental college Hospital and Research, Bangalore on the 27th of July, 2011.
24. CDE Program on "Stress in Dental practice-an insight" hosted by Dept of Community Dentistry, K.L.E.Society's Institute of Dental Sciences & Hospital , Bengaluru on 23/8/11
25. CDE Program on "Future Dental Professionals" (colgate IDA program) at K.L.E.Society's Institute of Dental Sciences & Hospital ,Bengaluru on 15/9/11.
26. CDE Program on Bind, Bond, Build held at Rajarajeswari Dental College and Hospital, Bangalore on 29th September, 2011.
27. 33rd Indian Society of Pedodontics and Preventive Dentistry conference held from 04th to 06th November, 2011 at Mangalore, INDIA.
28. CDE by Dept of Orthodontics & Oral Maxillofacial Surgery on "Current Advances in Maxillofacial & Orthodontic Surgery "held on 13th July, 2012.
29. Scientific Symposium on "Oral Systemic Health" at K.L.E Society's Institute of Dental Sciences & Hospital , Bengaluru on 19th July, 2012.
30. 20th -22nd July IDRR organized Dentistry 2012, at Palace grounds Bangalore.
31. Symposium on "Current Perspectives in Craniomaxillofacial Surgery and facial esthetic problems" at K.L.E.Society's Institute of Dental Sciences & Hospital , Bengaluru on 10th Oct, 2012.
32. PEDOSCOPE, 35th Annual Conference of ISPPD at Jaipur from 26th to 28th Sept, 2013.
33. Dentistry 2013 at Bangalore on 27th & 28th July ,2013.
34. PEDOFEST, 36th National ISPPD conference at Lucknow from 14th to 16th October, 2014.
35. Dentistry 2014 at Bangalore on 6th & 7th March, 2014.
36. PEDOZEST, 12th National post graduate convention at Tumkur from 26th to 28th February 2015.
37. PEDO ART, 37th National ISPPD conference at Raipur from 8th to 20th October, 2015.

SCIENTIFIC PRESENTATIONS:

1. Presented a video presentation (Directors Choice) for the 33rd Indian Society of Pedodontics and Preventive Dentistry conference held from 04th to 06th November, 2011 at Mangalore, India.
2. Presented a scientific poster (Clinical Periscope) titled Management of Mucocele of glands of Blandin and Nuhn by laser – presented at the 33rd Indian Society of Pedodontics and Preventive Dentistry conference held from 04th to 06th November, 2011 at Mangalore, India.
3. Presented a scientific poster (Clinical Periscope) titled CBCT – An Speculative Proposition for diagnosis presented at the 33rd Indian Society of Pedodontics and Preventive Dentistry conference held from 04th to 06th November, 2011 at Mangalore, India.

Curriculum Vitae

Name: Dr. Sumitra

Academic degrees - B.D.S, M.D.S

Additional Qualification - Diplomate, Indian Board of Orthodontics

Institutional affiliation and position -

Professor and Head

Department of Orthodontics and Dentofacial Orthopedics,

K.L.E Society's Institute of Dental Sciences,

Bangalore

Dental Council No: FID No- ORT00784

Karnataka State Registration No: 5382-A

Office Address: K.L.E Society's Institute of Dental Sciences
No. 20, Yeshwanthpur Suburb, Bangalore- 560022

Residence Address: 2921E-28, I Cross Road, II Stage,
Vijaynagar, Bangalore-560040

Telephone Numbers: Residence: 080-23508715
Clinic: 080-23508716
Mobile: 9448388716

Email address: sumayjr@gmail.com

Academic Qualifications

Post-Graduation:

Degree: M.D.S

Institution: Government Dental College

University: Bangalore

Year of Passing: 1996

Graduation

Degree: B.D.S

Institution: Government Dental College, Rohtak

University: Maharshi Dayanand University, Haryana.

Year of Passing: 1992

Teaching Experience - 19 years 10 months

Designation	Period	Institution
Lecturer	01-06-1996 to 30-04-1997 [11 months]	Rajarajeshwari Dental College and Hospital, Bangalore.
	15-05-1997 to 31-07-1998 [1 year and 2.5 months]	Babu Jagjeevanram Dental College and Hospital, Bangalore
	01-08-1998 to 01-08-1999 [1 year]	K.L.E Society's Institute of Dental Sciences Bangalore
Reader	02-08-1999 to 14-06-2004 [4 years 10 months]	K.L.E Society's Institute of Dental Sciences Bangalore
Professor	15-06-2004 to 01-07-2012	K.L.E Society's Institute of Dental Sciences Bangalore
Professor and HOD	02-07-2012 till date	K.L.E Society's Institute of Dental Sciences Bangalore

Academic Achievements

1. II Rank in the All India Post- graduate Entrance Exam -1993
2. Cleared the Phase III Examination of Indian Board of Orthodontics(IBO) and became a Diplomat of IBO in Dec 2008.

3. Dr. Prem Prakash Memorial Award for the best treated case in the Dec 2008 Examination of IBO

Publications

1. Third Molars And Late Mandibular Incisor Crowding – A Review; J Indian Orthod Soc. 2005; 38:100-111.
2. Assessment of Soft Tissue Profile Following Twin Block Appliance Therapy. J Indian Orthod Soc.2006; 39:80-88.
3. Treatment of Skeletal Class III Malocclusion with RME and Reverse Pull Headgear – A Case Report. J Indian Orthod Soc. 2009; 43:12-24.
4. Gentle jumper- A light force fixed functional appliance. Orthodontic Cyber Journal February, 2012.
5. MBT versatility in lower anteriors with premolar bracket. Orthodontic Cyber Journal March 2012.
6. Versatile MBT appliance and its effective management. Orthodontic Cyber Journal June, 2012.
7. Orthodontic extractions- When , where, what? Orthodontic Cyber Journal, July, 2012.
8. Orthodontic-surgical treatment of bilateral maxillary canine impaction. Contemp Clin Dent 2012; 3:363-6.
9. Clinical application of CBCT in orthodontics. Indian dentist research and review, May 2013.
10. Experience with contemporary Tip Edge Plus Technique – A case Report; IOSR JDMS 2014; 13: 12-17.
11. A simple clip for securing lingual retainer. IJOCR 2014; 12:30-32.
12. Non surgical rapid maxillary expansion in a young adult – KLES Dent J 2014; 3:1-5.
13. Non extraction management of class II Division 2 Malocclusion with Forsus FRD. KLES Dent J 2014;3: 6-11.
14. Management of class II div 1 subdivision in identical twins with different appliance systems. KLES Dent J 2014; 3:12-18.

15. Applicability of Bolton's Ratio to a Sample of South Indian population – KLES Dent J 2015;4:1-9.
16. Enamel surface evaluation after removal of orthodontic composite remnants by intraoral sandblasting technique and carbide bur technique : A three dimensional surface profilometry and scanning electron microscopic study. Journal of International Oral Health 2015; 7:34-39.
17. Indian Board of Orthodontics Case Report- Treatment of a severe Class II Division 1 malocclusion with twin –block appliance and PEA. J Indian Orthod Soc 2016;50:120-5.

Presentations - 22

Invited guest lecturers in CDE programs as a resource person - 12
 International Orthodontic conference presentations - 2
 National Conference presentations – 5
 KLES Institute of Dental Sciences - 3

Invited guest lecturers in CDE programs as a resource person - 12

1. K- SIR Arch wire – in a BOSG CDE program on Retraction Mechanics, Sept 2012.
2. Recent bonding materials - A BOSG CDE program on - Orthodontic Materials Revisited at GDC, Bangalore on 28th March 2013.
3. Objective assessment of treatment outcome- CDE program on Clinical excellence in Orthodontics 4th April 2014 at KLE Society's Institute of Dental Sciences, Bangalore.
4. Case documentation- CDE program on Clinical excellence in Orthodontics 4th April 2014 at KLE Society's Institute of Dental Sciences, Bangalore.
5. Current concepts of esthetic and functional factors in finishing - CDE program on Clinical excellence in Orthodontics 4th April 2014 at KLE Society's Institute of Dental Sciences, Bangalore.
6. Self assessment of treatment outcomes - IBO promotion program lecture – at Faculty of Dental Sciences, Sri Ramachandra University, Chennai on 23rd August 2014.
7. Interdisciplinary treatment – Periodontal- orthodontic interrelationship at a Zonal CDE program at Thejas Dental college and Hospital, NTR University, Tirupati on 4th July 2015.
8. Prosthodontic - orthodontic interrelationship- at a Zonal CDE program at Thejas Dental college and Hospital, NTR University, Tirupati on 4th July 2015.
9. Restorative - orthodontic interrelationship - at a Zonal CDE program at Thejas Dental college and Hospital, NTR University, Tirupati on 4th July 2015.
10. Recent advances in growth and development - at Faculty of Dental Sciences, Sri Ramachandra University, Chennai on 29th Jan 2016.
11. Treatment of a severe Class II division 1 malocclusion in the deceleration phase of

growth- at Indian Board of Diplomates' meet, Mumbai, on 2nd April 2016.

12. Tips to improve case finish - IBO Awareness program organized by Mumbai Orthodontic Study Group on 3rd April 2016.

International Orthodontic conference presentations - 2

1. Assessment of Soft Tissue Profile after Twin Block Appliance Therapy- A Cephalometric Study, presented in the 3rd World Edgewise Orthodontic Congress and 40th Indian Orthodontic Conference, Chandigarh, 13th Nov 2005.
2. Evidence based approach to treatment of severe skeletal Class II division 1 malocclusion in adolescents - presented in the 47th Indian Orthodontic Conference and Asia Pacific Orthodontic Conference held at New Delhi, Nov 2012.

Indian Orthodontic Society conference presentations - 5

1. Non-extraction treatment of Class II division 1 malocclusion with different functional appliances - Presented in the 42nd Indian Orthodontic Conference, held at Nagpur, 6th Jan, 2007.
2. Treatment of skeletal malocclusions with orthognathic surgery – Case reports presented in the 43rd Indian Orthodontic Conference held at Mumbai, Dec 2008
3. The Orthodontic- surgical Treatment of Impacted Canines - presented in the 45th Indian Orthodontic Conference held at Mangalore, Nov 2010.
4. Efficient Management of Skeletal Class III Malocclusion in Adolescents - Case Reports- presented in the 48th Indian Orthodontic Conference held at Ahmedabad, Nov 2013.
5. Interdisciplinary management of periodontally compromised cases- 49th IOC Kolkata 2014

KLES Institute of Dental Sciences - 3

1. Orthodontic awareness - a lecture for orthodontic week celebration - 4th October 2014 at KLE Society's Institute of Dental Sciences, Bangalore.
2. Innovative methods of teaching - A lecture at KLE Society's Institute of Dental Sciences, Bangalore 2015.
3. Orientation for the I MDS students - A lecture at KLE Society's Institute of Dental Sciences, Bangalore 2015.

Organized several CDE programs and workshops in Orthodontics and Teaching-Learning in dental education.

8. Undertaken project for Endocrinology & Diabetes Research Trust, Bangalore, involving identification of the beneficiaries (Govt. School Students) and distribution of education material such as Uniforms, Shoes & socks, Geometry Box, School Bags and model question papers to the 10th Standard students of Bangalore Rural District, Sringeri and Kolar Districts. since the academic year 2011-12 . Average annual expenditure is around Rs. 15 Lakhs, cost is borne by the Trust.

9. During the years 2000-2012 an average of 6000 children's per annum (from govt. school) in and around Bangalore were screened and treated under the Trust 's comprehensive healthcare scheme in the area of general medicine, Dental hygiene, diet and nutrition.

All the above diagnosis and treatment facilities are being provided to the beneficiaries free of cost.

Since the year 2013 the Dental Health awareness, screening and treatment program have been extended to the government school children of villages in Bangalore rural district and chikkaballapur district.

Trustee :

MAHATI Trust (R), Bangalore Established in 2011 with the objectives pertaining to women's healthcare, concentrating primarily on cancer of cervix which is predominantly high in India, conducting awareness camps, screening and pap-smear test and treatment wherever necessary. Since none of the above programs are financially or otherwise supported by Govt., the Trusts depend on contributions from philanthropic donors.

Associates :

- ❖ M. S. Ramaiah Medical College and Hospital
- ❖ M. S. Ramaiah Dental College and Hospital
- ❖ Endocrinology and Diabetes Research Trust
- ❖ Bangalore Diabetes Hospital
- ❖ Sankara Eye Hospital
- ❖ KLE Society's Institute of Dental Sciences
- ❖ Krishnadevaraya College of Dental Sciences
- ❖ Dr. Ramesh, Dr. Madhu, Dr. Mrs. Vathsala, Dr. Mrs. Sundara
- ❖ Dr. (Mrs) Padma Nanjappa, Dr. (Mrs) Sumangala Rao and Dr. C. N. Raghavendra Rao
- ❖ Dr. Ramana Rao, Eminent Cardiologist
- ❖ Dr. Eldose, Medical Officer, Sringeri (Chikkamagalur Dist.)
- ❖ Anand Diagnostic Centre, Bangalore
- ❖ Karnataka Cancer Society
- ❖ Biopharm Drugs and Pharmaceuticals
- ❖ Bentley and Remington Pvt. Ltd.
- ❖ Directorate of Collegiate Education
- ❖ Philanthropic Donors
- ❖ Deputy Director of Public Instructions, (Sarva Shikshana Abhiyana), Bangalore Rural District
- ❖ Kidwai Cancer Hospital, Bangalore

Family Details :

- Wife — Smt. Padma (Inspiration to all my activities)
- Daughters — Smt. Rajani Ramakrishna and Smt. Rekha Sheshadri

Other Information :

- Registered at **M.S. Ramaiah Medical College** for donation of my eyes and Body for Organs' transplantation and medical research.
- Registered at **ZCCK** for Cadaveric transplantation of my organs.

CURRICULUM VITAE

Name: MR. MADHUSUDHAN.G
Institutional Address: Department of Political Science
K.L.E.Society's S.Nijalingappa College
II Block, Rajajinagar, BANGALORE-560 010
Phone: 080 23325020, Fax: 080 23320902
Residential Address: #19/19, 4th cross, Bapuji layout, Vijayanagar, Bangalore-40
Email: madhusudhan.kle@gmail.com **Mobile:** 91+9986368438

ACADEMIC RECORD:

Degree secured	University/Board	Year	Subjects	Roll of Honors
MA	Bangalore University	2006	Political science	First Class
B.Ed	Bangalore University	2010	Education	First Class
MPhil	MKU	2009	Public Administration	First Class
Bachelor of Arts	Bangalore University	2004	History, Economics, Political Science	First Class
Pre-University (PUC)	PU Board, Bangalore	1998	Science	FIRST CLASS
S.S.L.C.	Karnataka Higher Secondary Board, Bangalore	1996	Science Mathematics, Social Science	First Class

Teaching Experience:

Since 2006 till date, I have been in the Teaching field for the under graduate and Integrated MTA graduates, Department of Political Science and Department of MTA, Bangalore University.

PERSONAL DETAILS

Address: #19/19, 4th Cross, Bapuji Layout, Vijayanagar, Bangalore 560040
DOB: 22nd May 1980
Languages known: English, Hindi, Kannada.
References: Available on request

Declaration

I hereby declare that the above information is true and correct to the best of my knowledge. I am sure that I will fulfill my duties with my sincere efforts and honest.

(MADHUSUDHAN.G)

CURRICULUM VITAE

PERSONAL DETAILS

Name : **Shyla V**

Address : "AVIGHNA", #32, 3rd A cross
2nd stage Satyanarayana layout
JC Nagar, Bangalore – 560086

Telephone : 0091-80-23595894 (Res)
9980095894 (Mob)

E-mail : shylaramesh@yahoo.com

Date of Birth : 30-Jan-1970

Nationality : Indian

Registration : KMC Registration, 36118

Medical Qualifications : **M.B.B.S.**
Kempegowda Institute of Medical Sciences,
Bangalore
April 1992

Post Graduate Qualifications: **MD (Pathology)**
Bangalore Medical College
April 1999

PGDHHM(Symbiosis centre for
health care) May 2012

Professional Experience

Experience Summary

1. Kle Society's institute of Dental Sciences and Hospital

Designation: Lecturer

Duration: From May 2009 till Date

Description: KLE Dental college is an undergraduate and post graduate Institute with a fully equipped medical and dental departments

Responsibilities:

- I am responsible for conducting Theory and Practical sessions in all aspects of Pathology for the undergraduates and post graduates
- My teaching sessions includes both small and large group teaching
- I am responsible for conducting Internal Assesments and being an Expert Assistant for the University Examinations
- I am also incharge of updating the departmental laboratory and the Museum.

2. Kaade Hospital, Bangalore

Designation: Consultant and Head of the department

Duration: Dec 2012 Till Date

Description:

KAADE Hospital is a multispeciality hospital with state of art facilities catering to all advanced surgical and medical needs.

Responsibilities

Complete in charge of Haematology, Clinical Pathology, Cytology, Biochemistry and Microbiology departments.

- Supervision of sample collection/analysis, interpretation and reporting for above departments.
- Responsible for staff management.
- Responsible for maintaining lab documents as per ISO 9000 standards and involved in renewal of ISO 9000 certification for 2004-20 05.
- Responsible maintaining the lab standards of various analytes for 'Inter Laboratory Quality Assurance' and 'External Quality Assurance'.
- **Preparing for NABH/NABL Accreditation**

3. Indus Westside Hospital, Metropolis

Designation: Consultant and Head of the department

Duration: Dec 2009 To Aug 2012

Description:

Indus Westside Hospital, is a multispeciality hospital with state of art facilities catering to all advanced surgical and medical needs.

Responsibilities

Complete in charge of Haematology, Clinical Pathology, Cytology, Biochemistry and Microbiology departments.

- Supervision of sample collection/analysis, interpretation and reporting for above departments.
- Responsible for staff management.
- Responsible for maintaining lab documents as per ISO 9000 standards and involved in renewal of ISO 9000 certification for 2004-20 05.
- Responsible maintaining the lab standards of various analytes for 'Inter Laboratory Quality Assurance' and 'External Quality Assurance'.
- **Preparing for NABH/NABL Accreditation**

4. Kanva Diagnostic Sevices Pvt. Ltd., Bangalore

Designation: Chief Pathologist

Duration: From December 2003 to July 2005 : May 2007 Till Date

Description:

Kanva is a multi faculty, high tech diagnostic centre, fully automated laboratory, radiology, super speciality consultations with a daily inflow of 450 to 500 patients.

Responsibilities:

- Complete in charge of Haematology, Clinical Pathology, Cytology, Biochemistry and Microbiology departments.
- Supervision of sample collection/analysis, interpretation and reporting for above departments.
- Responsible for staff management.
- Responsible for maintaining lab documents as per ISO 9000 standards and involved in renewal of ISO 9000 certification for 2004-20 05.
- Responsible maintaining the lab standards of various analytes for 'Inter Laboratory Quality Assurance' and 'External Quality Assurance'.
- .

5. St.Teresa Hospital, Bangalore

Designation: Chief Pathologist

Duration: From August 2001 to December 2003.

Description:

St. Teresa hospital is a multi speciality 100-bedded hospital with neo-natal ICU/CCU and a dialysis unit.

Responsibilities:

- Establishing a full-fledged laboratory with Histopathology, Haematology, Clinical Pathology, Cytology, Biochemistry and Microbiology departments.
- Responsible for installation of high end instruments of various lab departments.
- Responsible for staff management.
- Organizing Clinico-pathological meetings.
-

6. Citi Hospital, Bangalore

Designation: Consultant Pathologist

Duration: From January 2003 to December 2003.

Description:

Citi Hospital is a multi speciality 60-bedded hospital with 24 hrs emergency and ICU

Responsibilities:

- Responsible for supervision and reporting of various tests of Histopathology, Haematology, Clinical Pathology, Cytology, Biochemistry and Microbiology departments.
- Up gradation of laboratory technology and expertise.

7. Panacea Hospital, Bangalore

Designation: Consultant Pathologist

Duration: From August 2001 to April 2003.

Description:

Panacea Hospital is a multi speciality 60-bedded hospital with 24 hrs emergency and trauma centre.

Responsibilities:

- Responsible for supervision and reporting of various tests of Histopathology, Haematology, Clinical Pathology, Cytology, Biochemistry and Microbiology departments.

8. Apoorva Diagnostic Centre, Bangalore**Designation: Consultant Pathologist**

Duration: From August 1999 to December 2000.

Description:

Apoorva is a multi speciality diagnostic centre with fully automated laboratory, Radiology and super speciality consultation centre with daily inflow of 150 to 200 patients.

Responsibilities:

- Responsible for supervision and reporting of various tests of Histopathology, Haematology, Clinical Pathology, Cytology and Biochemistry departments.

Research Experience

Carried out a study titled "Clinicopathological study of resected lung specimens" (For MD dissertation)

Academic Activities

- Presented an oral paper titled "Clinicopathological study of inflammatory lesions in resected lung specimens" at the state level conference held in March 98 at St. Johns Medical College under the auspices of Indian Association of Pathologists and Microbiologists.
- Took active participation in preparing an oral paper for Nation Conference held at IISc, Bangalore during December 1996 under the auspices of Indian Association of Pathologists and Microbiologists.
- Member of scientific committee, in conducting and organising CME programmes in pathology during 1995 – 1998 under the auspices of Academic council of Bangalore Medical College and Combined Hospitals, Bangalore.

Courses/Conferences

- Cytology workshop organized by "Indian Academy of Cytologists", during November 1995 held at Division of Cytology, St Johns Medical College, Bangalore.
- Seminar on paediatric haemato oncology organized by IAPM during December 1995.
- 36th Annual Conference by Indian Society of haematology and blood transfusion during December 1995.
- Annual Conference of Karnataka chapter of IAPM organized at St. Johns Medical College, Bangalore during February 1998.
- Continuing Medical Education (CME) programme in Pathology at Bangalore Medical College organized by Academic Society, Bangalore Medical College.

- XV CME & PG course in Pathology, conducted by National Academic of Medical sciences (India) & Medical Education and Research Trust held during June 1997 at JNMC, Belgaum.
- XVI CME & PG course in Pathology held during June 1998 at JNMC, Belgaum.
- Haemato-oncology, CME & Seminar held during 2001 at Kidwai Memorial Institute of Oncology
- 4th Sysmex – Transasia International scientific seminar on “Update in Lab Haematology” during December 2004.
- Immuno-haematology CME conducted at Kidwai institute of oncology, Bangalore on 4th and 5th of October 2006.
- Participated in the Training Workshop on **GOOD LABORATORY PRACTICES** held at Bangalore Institute Of Oncology, Bangalore on 3rd Dec 2006
- Attended hands on workshop in Blood Bank techniques conducted by Diamed Technologies Private Limited at Rotary TTK Blood Bank on 26th and 27th March 2007

Prizes and Awards

Achieved proficiency in the “Annual Paediatric Quiz” conducted by Indian academy of Paediatrics at 5th Quiz held during 1991/92.

BBMC-5739

A35-M-M0-MA-27

ಬೆಂಗಳೂರು ವಿಶ್ವವಿದ್ಯಾಲಯ
Bangalore University
certifies that

Shyla V..... ಅವರು

has been duly admitted to the Degree of

ಡಾಕ್ಟರ್ ಆಫ್ ಮೆಡಿಸಿನ್
Doctor of Medicine

ಪದವಿಗೆ ಅಗತ್ಯವಾದ ಅರ್ಹತೆಗಳನ್ನು ಪೂರೈಸಿ ಪರಿಗಣಿತವಾಗಿರುವ ಕಾರಣ
in recognition of the fulfilment of requirements
ಮೇಲೆ ಕಾಣಿಸಿದ ಪದವಿಗೆ ಅವರನ್ನು ಅಂಗೀಕರಿಸಲಾಗಿದೆ. ಆ ಪದವಿಯ ವಿವರಗಳು ಹೀಗಿವೆ :
for the said degree as follows :

April 1999

ಪರೀಕ್ಷೆಯ ವರ್ಷ.....

Year of Examination :

Pathology

ಅಧ್ಯಯನದ ವಿಷಯ.....

Subjects :

Pass

ಪಡೆದ ವರ್ಗ.....

Class :

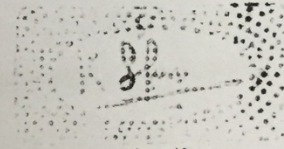


ವಿಶ್ವವಿದ್ಯಾಲಯದ ಅಧಿಕಾರ ಮುದ್ರೆಯೊಡನೆ ನೀಡಲಾಗಿದೆ
Given under the seal of the University



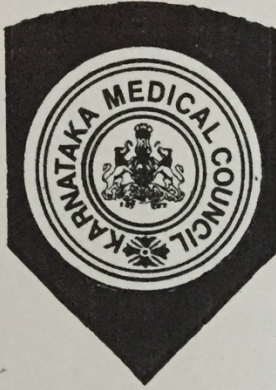
ಬೆಂಗಳೂರು
Bangalore

ದಿನಾಂಕ
Date 07.03.2000



ಕುಲಪತಿ
Vice-Chancellor

Karnataka Medical Council



No. 36, 118.



Karnataka Medical Council

Karnataka Medical Council
No. 40, 1 Floor, Lakshmi Complex,
K. R. Road, Bangalore - 560 002.

Dated 26th April 1993.

CERTIFICATE OF REGISTRATION

(UNDER THE KARNATAKA MEDICAL REGISTRATION ACT 34 OF 1961)

Name SHYLA.V.
 Father's Name LAKSHMI NARASIMHA SASTRY.V.N.
 Qualifications M.B.B.S. (Bangalore.U.) April 1993.
M.D. (PATHOLOGY) (Bangalore.U.) April 1999.
Bangalore Medical College B'lore.
 Date of Registration 26th April 1993.
 Address 1280, III Cross, Ashokanagar, BSK 1st Stage, Bangalore-560 050,
Karnataka.

S. V. Jayaraman
Registrar
Karnataka Medical Council

I do hereby certify that this is a true copy of the entry of the above-specified name in the Medical Register and the above Registration is PERMANENT

IMPORTANT NOTICE

- 1 Report change of address and additional qualifications promptly.
- 2 All enquiries made by the Registrar should be answered without fail.
- 3 All persons Registered under this Act are legally qualified to practice Modern Scientific Medicine, Surgery, Obstetrics and Gynaecology.
- 4 Shall abide by Code of Medical Ethics framed from time to time.

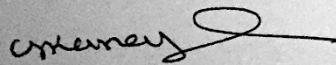
C. Shivaraman
(C. SHIVARAMAN)
Registrar

Curriculum Vitae

Name : Chidanand. Shankar. Kanade
Date of Birth : 01.07.1961
Age : 55 Years
Qualification : B A
Date Appointment : 02.09.1985
Length of Service : 30 Years
Designation : Office Superintendent
Office Address : K L E Society's Hostels,
NO.20, Industrial Suburub, 2nd Stage,
Yeshwanthpue, Tumkur Road, Bengaluru-560 022.
Ph: 080- 23470449

Postal Address : Chidanand S Kanade
No.101, 12thCross, Ist ' K ' Block,
Rajajinagar Bengaluru – 10.

E Mail ID : chidanandkanade@gmail.com
Mobile No : 9945388224



Confidentiality and Conflict of Interest Document for IEC Members

In recognition of the fact, that I, (name and designation).....

.....
herein referred to as the –Undersigned, have been appointed as a member of the Institutional Ethics Committee (IEC), would be asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;

Whereas, the appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative of a home province/territory/community nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of an IEC member is to independently review research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

The undersigned, as a member of the IEC is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets (–information) in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that the performance of this agreement is consistent with the Institute’s policies and any contractual obligations they may have to third parties.

Conflict of Interest

It has been recognized that the potential for conflict of interest will always exist but I have faith in the IEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

In accordance of the policy of the IEC, I shall not participate in the review, comment or approval of any activity in which I have a conflict of interest, except to provide information as requested by the IEC.

I will disclose to the Chairperson of the IEC any actual or potential conflict of interest that I may have in relation to any particular proposal submitted for review by the committee, and abstain from participation in discussions or recommendations in respect of such proposals.

Examples of conflict of interest cases may be any of the following:

- ◆ A member is involved in a potentially competing research program.
- ◆ Access to funding or intellectual information may provide an unfair competitive advantage.
- ◆ A member’s personal biases may interfere with his or her impartial judgment.

If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol. The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IEC member(s) in question. The committee may elect to investigate the applicant’s claim of the potential conflict.

In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation (–Confidential Information). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the access to it, as per the right to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee’s mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any agenda items) to the Bioethics cell upon termination of my functions as a Committee member.

Whenever I have a conflict of interest, I shall immediately inform the committee not to count me toward a quorum for consensus or voting.

I, have read and I accept the aforementioned terms and conditions as explained in this Agreement.

Signature

Name _____

Date: _____

Conflict of Interest Declaration for IEC Members (During IEC meeting)

To,
The Member Secretary
Institutional Ethics Committee
KIDS-B, Bangalore.

Conflict of Interest

I hereby declare that I have no conflict of interest in my project.

- 1.
- 2.
- 3.
- 4.

Signature of member

Name _____

Date _____

**Confidentiality Document Form for Independent
Consultants**

I,.....
.....

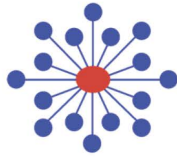
.....(name and designation) as a non-member of IEC understand that the copy (ies) given to me by the IEC is (are) confidential. I shall use the information only for the indicated purpose as described to the IEC and shall not duplicate, give or distribute these documents to any person(s) without permission from the IEC.

Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as confidential.

Signature

Name

Date:



NIDA Clinical Trials Network

Certificate of Completion

is hereby granted to

Ashwin Prabhu

to certify your completion of the six-hour required course on:

GOOD CLINICAL PRACTICES

MODULE:

Introduction
 Institutional Review Boards
 Informed Consent
 Confidentiality & Privacy
 Participant Safety & Adverse Events
 Quality Assurance
 The Research Protocol
 Documentation & Record-Keeping
 Research Misconduct
 Roles & Responsibilities
 Recruitment & Retention
 Investigational New Drugs

STATUS:

N/A
 Passed
 Passed
 Passed
 Passed
 Passed
 Passed
 Passed
 Passed
 Passed
 Passed
 Passed

Course Completion Date: 1 April 2016

CTN Expiration Date: 1 April 2019

Tracee Williams, Training Coordinator
 NIDA Clinical Coordinating Center

This training has been funded in whole or in part with Federal funds from the National Institute on Drug Abuse, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN27201201000024C.



GEORGE CLINICAL
Scientific and Operational Excellence
in Clinical Trials



This is to certify that

Dr. Vijayalakshmi I. Balekundri

has completed basic training in
Good Clinical Practice

&


Good Documentation Practice

Training duration: 3 hours


The topics covered in the training sessions were:

History and Principles of GCP, Informed Consent Process, Documentation Auditing and Inspections, Adverse and Serious Adverse Events, Roles and Responsibilities, Monitoring, Essential Documents, Drug Accountability and Compliance.

Dr. Srivatsa G
Principal
Constituent Authority, IEC KIDS-B


Dr. Ashwin Prabhu
Member Secretary
IEC KIDS-B


Dr. Sudhir R Patil
Course Co-ordinator
Member, IEC KIDS-B


Dr. Ramesh Thinnmaiah
Course Instructor & Trainer
Regional Project Manager, George Clinical



GEORGE CLINICAL
Scientific and Operational Excellence
in Clinical Trials



This is to certify that

Dr. Ashwin Prabhu

has completed basic training in
Good Clinical Practice

&

Good Documentation Practice

Training duration: 3 hours


The topics covered in the training sessions were:

History and Principles of GCP, Informed Consent Process, Documentation Auditing and Inspections, Adverse and Serious Adverse Events, Roles and Responsibilities, Monitoring, Essential Documents, Drug Accountability and Compliance.

Dr. Srivatsa G
Principal
Constituent Authority, IEC KIDS-B


Dr. Ashwin Prabhu
Member Secretary
IEC KIDS-B


Dr. Sudhir R Patil
Course Co-ordinator
Member, IEC KIDS-B


Dr. Ramesh Thimmaiah
Course Instructor & Trainer
Regional Project Manager, George Clinical



GEORGE CLINICAL
Scientific and Operational Excellence
in Clinical Trials



This is to certify that

Dr. Sudhir R. Patil

has completed basic training in
Good Clinical Practice

&

Good Documentation Practice

Training duration: 3 hours

The topics covered in the training sessions were:

History and Principles of GCP, Informed Consent Process, Documentation Auditing and Inspections, Adverse and Serious Adverse Events, Roles and Responsibilities, Monitoring, Essential Documents, Drug Accountability and Compliance.

Dr. Srivatsa G
Principal
Constituent Authority, IEC KIDS-B

Dr. Ashwin Prabhu
Member Secretary
IEC KIDS-B

Dr. Sudhir R Patil
Course Co-ordinator
Member, IEC KIDS-B

Dr. Ramesh Thirumalaiah
Course Instructor & Trainer
Regional Project Manager, George Clinical



GEORGE CLINICAL
Scientific and Operational Excellence
in Clinical Trials



This is to certify that

Dr. Sandhya Devi Patil

has completed basic training in
Good Clinical Practice
&

Good Documentation Practice

Training duration: 3 hours

The topics covered in the training sessions were:

History and Principles of GCP, Informed Consent Process, Documentation Auditing and Inspections, Adverse and Serious Adverse Events, Roles and Responsibilities, Monitoring, Essential Documents, Drug Accountability and Compliance.

Dr. Srivatsa G
Principal
Constituent Authority, IEC KIDS-B

Dr. Ashwin Prabhu
Member Secretary
IEC KIDS-B

Dr. Sudhir R Patil
Course Co-ordinator
Member, IEC KIDS-B

Dr. Ramesh Thimmaiah
Course Instructor & Trainer
Regional Project Manager, George Clinical



GEORGE CLINICAL
Scientific and Operational Excellence
in Clinical Trials



This is to certify that

Dr. Sumitra

has completed basic training in

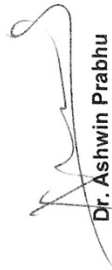
**Good Clinical Practice
&
Good Documentation Practice**

Training duration: 3 hours

The topics covered in the training sessions were:

History and Principles of GCP, Informed Consent Process, Documentation Auditing and Inspections, Adverse and Serious Adverse Events, Roles and Responsibilities, Monitoring, Essential Documents, Drug Accountability and Compliance.

Dr. Srivatsa G
Principal
Constituent Authority, IEC KIDS-B


Dr. Ashwin Prabhu
Member Secretary
IEC KIDS-B


Dr. Sudhir R Patil
Course Co-ordinator
Member, IEC KIDS-B


Dr. Ramesh Thirumalaiah
Course Instructor & Trainer
Regional Project Manager, George Clinical



GEORGE CLINICAL
Scientific and Operational Excellence
in Clinical Trials



This is to certify that

Mr. Gundu Rao H.L

has completed basic training in

Good Clinical Practice

&


Good Documentation Practice

Training duration: 3 hours


The topics covered in the training sessions were:

History and Principles of GCP, Informed Consent Process, Documentation Auditing and Inspections, Adverse and Serious Adverse Events, Roles and Responsibilities, Monitoring, Essential Documents, Drug Accountability and Compliance.

Dr. Srivatsa G
Principal
Constituent Authority, IEC KIDS-B


Dr. Ashwin Prabhu
Member Secretary
IEC KIDS-B


Dr. Sudhir R Patil
Course Co-ordinator
Member, IEC KIDS-B


Dr. Ramesh Thirumalaiah
Course Instructor & Trainer
Regional Project Manager, George Clinical



GEORGE CLINICAL
Scientific and Operational Excellence
in Clinical Trials



This is to certify that

Dr. Nancy Suresh Shetty

has completed basic training in
Good Clinical Practice

&

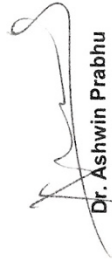
Good Documentation Practice

Training duration: 3 hours

The topics covered in the training sessions were:

History and Principles of GCP, Informed Consent Process, Documentation Auditing and Inspections, Adverse and Serious Adverse Events, Roles and Responsibilities, Monitoring, Essential Documents, Drug Accountability and Compliance.

Dr. Srivatsa G
Principal
Constituent Authority, IEC KIDS-B


Dr. Ashwin Prabhu
Member Secretary
IEC KIDS-B


Dr. Sudhir R Patil
Course Co-ordinator
Member, IEC KIDS-B


Dr. Ramesh Thinnmaiah
Course Instructor & Trainer
Regional Project Manager, George Clinical



GEORGE CLINICAL
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in Clinical Trials



This is to certify that

Mr. Madhusudhan G.

has completed basic training in

Good Clinical Practice

&

Good Documentation Practice

Training duration: 3 hours

The topics covered in the training sessions were:

History and Principles of GCP, Informed Consent Process, Documentation Auditing and Inspections, Adverse and Serious Adverse Events, Roles and Responsibilities, Monitoring, Essential Documents, Drug Accountability and Compliance.

Dr. Srivatsa G
Principal
Constituent Authority, IEC KIDS-B

Dr. Ashwin Prabhu
Member Secretary
IEC KIDS-B

Dr. Sudhir R Patil
Course Co-ordinator
Member, IEC KIDS-B

Dr. Ramesh Thirumalaiah
Course Instructor & Trainer
Regional Project Manager, George Clinical



GEORGE CLINICAL
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in Clinical Trials



This is to certify that

Dr. Shyla V.

has completed basic training in

Good Clinical Practice

&

Good Documentation Practice

Training duration: 3 hours

The topics covered in the training sessions were:

History and Principles of GCP, Informed Consent Process, Documentation Auditing and Inspections, Adverse and Serious Adverse Events, Roles and Responsibilities, Monitoring, Essential Documents, Drug Accountability and Compliance.

Dr. Srivatsa G
Principal
Constituent Authority, IEC KIDS-B

Dr. Ashwin Prabhu
Member Secretary
IEC KIDS-B

Dr. Sudhir R Patil
Course Co-ordinator
Member, IEC KIDS-B

Dr. Ramesh Thirumalaiah
Course Instructor & Trainer
Regional Project Manager, George Clinical



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in Clinical Trials



This is to certify that

Mr. Chidananda S. Kanade

has completed basic training in
Good Clinical Practice

&


Good Documentation Practice

Training duration: 3 hours

The topics covered in the training sessions were:

History and Principles of GCP, Informed Consent Process, Documentation Auditing and Inspections, Adverse and Serious Adverse Events, Roles and Responsibilities, Monitoring, Essential Documents, Drug Accountability and Compliance.

Dr. Srivatsa G
Principal
Constituent Authority, IEC KIDS-B


Dr. Sudhir R Patil
Course Co-ordinator
Member, IEC KIDS-B


Dr. Ramesh Thimmiah
Course Instructor & Trainer
Regional Project Manager, George Clinical

UNDERTAKING BY THE ETHICS COMMITTEE

1. Full name, address and title of the Chairman

Dr. Vijayalakshmi I. Balekundri M.B.B.S, MD (Gen med), DM(Cardio), DSc.	Aditi, 44 A, V Main Road, Vijayanagar II stage, Hampinagar, Bengaluru-560 040	Chairperson /Clinician (Pediatric Cardiologist ;Non institutional)
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2. Name and address of the office of Ethics Committee

NAME OF COMMITTEE: **Institute Ethics Committee, KLE Society's Institute of Dental Sciences, Bangalore.**

FULL POSTAL ADDRESS: **Room No. 5, Department of Periodontics, KLE Society's Institute of Dental Sciences, #20, Yeshwanthpur Suburb, Tumkur Road, Bangalore-560022.**

3. Names, address, qualifications & designation of the other members of the Ethics Committee.

Dr.Ashwin Prabhu	MDS	Flat 105, Bindiya residency, 24 th Main, 6 th Phase , JP Nagar, Bangalore- 560078	Member Secretary/Clinician
Dr. Sudhir R Patil	MDS	Flat S3-Block B, No.36-39, Reliance Mansions, Hariram Aildas Layout, Vijaynagar, Bangalore -560040	Clinician
Dr Sandya Devi Patil	MDS	Flat S3-Block B, No.36-39, Reliance Mansions, Hariram Aildas Layout, Vijaynagar, Bangalore -560040	Clinician
Dr. Sumitra	MDS	2921E, I cross road, II stage, Vijaynagar Bangalore-40	Clinician
Mr. Gundu Rao H L	Diploma in craftsmanship	#612, 3 rd cross, 2 nd stage A block, RHCS Layout, Srigandhada kavalu, Bangalore -91	Social Worker

Mrs. Nancy Suresh Shetty	B.A, L.L.B(M.A) LLM	No.23, Anantharam Layout, 6 th cross, Lingarajpuram, St. Thomas Town, Bangalore-84	Legal expert
Mr. Madhusudhan G	B.A, M.A, B.Ed, M. Phil.	#19/19 4 th cross, Bapuji Layout, Vijaynagar , Bangalore -560040	Social Scientist/ Philosopher
Dr. Shyla V.	MBBS, MD (Path), PGDHHM	"AVIGHNA", #32, 3rd A cross ,2nd stage Satyanarayana layout,JCNagar , Bangalore – 560086	Pathologist/Basic Medical Scientist
Mr. Chidananda S Kanade	BA	No.101, 12 th Cross, 1 st K block, rajajinagar, Bangalore -10	Lay Person from community

4. Commitments:

- (i) The Committee shall review and accord its approval to a clinical trial and also carry ongoing review of the 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.
- (ii) In the case of any serious adverse event occurring to the clinical trial subjects during the clinical trial, the Committee shall analyse and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.
- (iii) The Committee shall allow inspectors or officials authorised by the Central Drugs Standard Control Organisation 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.
- (iv) We agree to maintain adequate and accurate records 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).

(Signature of the Chairman)

(Signature of the Member secretary)

Date: