Standard Operating Procedures
For
Institutional Ethics Committee

S B Patil Institute for Dental Sciences and Research, Bidar

PREPARED BY

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Research-Institute Ethics Coommittee
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CONTENTS

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I Short Title and Scope:

The following may be called as "Standard Operating Procedures for the Institutional ethics committee (IEC) of S B Patil Institute for Dental Sciences and Research (SBPIDSR), Bidar". The present SOP covers functioning of Ethics Committee reviewing all research on Human subjectsdone at SBPIDSR as well as those done at other locations under the aegis of a principle investigator / co-investigator employed at SBPIDSR.

II Name of the Ethics Committee :

Institutional Ethics Committee (IEC), S B Patil Institute for Dental Sciences and Research (SBPIDSR), Bidar

Address of the Office of the Ethics Committee

The Member Secretary
Institutional Ethics Committee
S B Patil Institute for Dental Sciences and
Research, Naubad, BIDAR – 585402
Phone No: 08482-232101
Fax No: 08482-232101
Email ID: principalsbpdch@yahoo.co.in

III Objective:

The objective of this Standard Operating Procedures of the Institutional ethics committee (IEC) of SBPIDSR, Bidar is to maintain effective functioning of the SBPIDSR- 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 Terms of reference: The Ethics committee is mandated to examine research proposals where research is to be wholly or partially carried out at SBPIDSR to ensure that research iscarried out in accordance with ethical principles.

To ensure that the research projects carried out at SBPIDSR

- Are sound in design, have statistical validity and are conducted according to the ICMR and ICH / GCP guidelines.
- Do not compromise safety of the patients or volunteers.
- Are conducted under the supervision of medical persons with the required expertise.
- Include solely, patients who have given voluntary and informed consent.

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V Authority under which the Ethics Committee has been constituted, Membership Requirements, the term of reference, conditions of appointment and the quorum required.

1. **Authority under which the Ethics Committee has been constituted**: The Chairman, Somnath Education Trust of S B Patil Institute for Dental Sciences and Research (SBPIDSR), Bidar, is the competent authority for constitution of the IEC. The Principal is authorized to nominate members in consultation with the Chairperson of the IEC among those who possess the qualifications and experience as per the norms prescribed under Drugs and Cosmetics Rules.
2. **Membership Requirements:**
   Institutional Ethics committee will be constituted with the following:
   i. Chairperson, nominated by the Principal, an expert fromoutside the institute.
   ii. Member secretary – Institutional
   iii. Medical scientists from the Institute – 2 members
   iv. Subject Expert(Members)- 2 members
   v. Non Medical Scientific Member – 01 member
   vi. Non Medical : Social Scientist/ philosopher/ethicist/theologian – 01member
   vii. Legal expert-01 member
   viii. Lay person- 01 member
   ix. Additional member(s) in any of the above categories as required

Presence of at least one woman on the committee is compulsory.

Medical Scientists shall hold a Post Graduate Degree in Medicine/Dentistry of MD/ MS/PhD. The Non-Medical Scientific members are required to have a Ph.D in Life Sciences / Veterinary Sciences. Legal Expert is required to be an Advocate with basic qualification of B.L. All members are required to have good moral character and should not have been convicted for any offence.

Chairperson:

a. The Chairperson of the Committee should be from outside the Institution to maintain the independence of the Committee.
b. The Chairperson is responsible for conducting all committee meetings, and leads all discussions and deliberations pertinent to the review of research proposals.
c. The Chairperson presides overall administrative matters pertinent to the committee's functions.

Member Secretary:

a. The Member Secretary should be a Medical Scientist who belongs SBPIDSR and should conduct the business of the committee.
b. In consultation with the Chairperson, the Member Secretary will be responsible for the following functions.

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c. Receiving all research proposals.
d. Forwarding all materials for review by the committee members.
e. Preparation and dissemination of agenda for all committee meetings (10 days prior to the meeting date).
f. Inviting special attendees/expert, from relevant specialities to the scheduled meetings, if needed.
g. Preparation and circulation of minutes (within 14 days of the meeting).
h. Notification of review outcome to Principal Investigator of research proposals.
i. Retention and safekeeping of all records and documentation.
j. Performance of other duties assigned by the Chairperson.

Procedure for appointment of Members:

The Principal after appointing the chairperson shall, in consultation with the Chairperson, nominate the members of IEC, who have the qualification and experience to review and evaluate the science, medical aspect and ethics of the proposed study.

- The normal term for IEC member will be for 24 months.
- Principal in consultation with chairperson and member secretary can renew the appointment of the member on the basis of Contribution.
- During the term, Principal in consultation with chairperson and member secretary can disqualify any member if the contribution is not adequate and, or there is long period of (member) non availability.
- Member can discontinue from membership of IEC after giving at least 1 month advance notice.
- Principal can replace the member of IEC as and when required.
- Each member is required to sign the declaration and confidentiality agreement regarding IEC activities.
- Conditions of appointment: Non institutional committee members are paid an honorarium for each meeting.

VI The quorum required:

The quorum required shall be a minimum of 5 members. It should include both medical and non-medical members, with at least one of the members present being not affiliated to SBPIDSR.

The quorum for review of clinical trial or bioavailability or bioequivalence protocol and related documents shall be at least five members with the following representations. (i) medical scientist (preferably a pharmacologist); (ii) clinician, (iii) legal expert; (iv) social scientist or representative of non- governmental voluntary agency or philosopher or ethicist or theologian or a similar person; (v) lay person.

VII Type of clinical research reviewed by the committee (e.g. pharmaceuticals, devices, epidemiological, retrospective, herbals, etc.,)

Drug trials, Prospective clinical studies, on both dental and surgical patients and blood and pathology specimens, epidemiological studies, retrospective studies that are conducted by the students and staff of S B Patil institute for Dental Sciences and Research, Bidar, Karnataka, India (SBPIDSR)

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VIII Documents reviewed for every clinical trial protocol including informed consent documents.

(a) The appropriateness of the study design in relation to the objectives of the study, the statistical methodology, and the potential for reaching sound conclusions with the smallest number of research participants.
(b) Consent form in English and local language (KANNADA) case of studies on human subjects.
(c) Source of funding for the clinical trial.
(d) Description of the ethical consideration involved in the research.
(e) Case report forms, diary cards, proformas and other questionnaires intended for research participants.
(f) Investigator's curriculum vitae.
(g) A Statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants.
(h) A description of the arrangements for indemnity, if applicable.
(i) A description of the arrangements for insurance coverage for research participants, if applicable.
(j) A statement of agreement to comply with ethical principles set out in relevant guidelines.
(k) All previous IEC's decisions (e.g., those leading to a negative decision or modified protocol) and by other regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on that account. The reasons for previous negative decisions must be provided.
(l) Justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.
(m) The justification for use of control arms
(n) Criteria for prematurely withdrawing the research participants
(o) Criteria for suspending or terminating the research as a whole
(p) The adequacy of provisions made for monitoring and auditing the conduct of the research Including data safety monitoring committee
(q) The adequacy of the site, including the supporting staff, available facilities and emergency procedure.
(r) The manner in which the results of the research will be reported and published.

IX Procedure for submission of application for ethics review:

1) The Principal Investigator has to submit an application in a prescribed format along with study protocol for the review of the IEC.
2) Application can be submitted to the office of the Chairman, IEC, S B Patil Institute for Dental Sciences and Research (SBPIDSR), Bidar, on any working day.
3) All the proposals and documents must be submitted in English language, at least 3 weeks in advance from the schedule date of IECmeeting.
4) Eleven (11) copies of study proposal (with all documents) must be submitted along with application form duly signed and dated by the investigator(s)
5) On receipt, the applications will be acknowledged with IEC registration number to be used for all future correspondence and reference.

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6) Thesis of MDS/Ph.D Courses involving ethical issues also need IEC clearance.

7) Every application has to be routed through the concerned Head of the Department to the IEC.

X The procedures (SOP) to be followed by the committee during meetings and while taking decisions:

(a) Meeting of the Ethics committee will be held monthly. Applicant, sponsor or investigator may be invited to make a slide presentation on the proposal or elaborate on specific issues.

(b) A decision will be taken only when sufficient time has been allowed to the Principal investigator for presentation of protocol and to the committee for review and discussion.

(c) The IEC will evaluate the possible risks to the subject with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue.

(d) A decision will only be taken at meetings where the quorum is complete. Independent expert may be invited to the meeting or to provide written comment, subject to applicable confidentiality agreement.

(e) Members will be given 10 days time in advance to review study proposals and the relevant documents.

(f) IEC meetings will be minuted and all the proceedings and deliberation will be documented.

(g) At the end of each IEC meeting, signatures from each member who has participated will be obtained on the final draft of the minutes of meeting.

(h) Decision will be taken only after reviewing a complete application with all the required documents necessary for the proposal.

(i) Only members who participated in review and discussion will participate in decision.

(j) Where ever possible, the decision will be arrived at through consensus not by vote, but when a consensus appears unlikely voting may be performed. Decision will be taken by simple majority of those attending.

(k) Member having the conflict of interest will indicate to the chairman prior to the review of application and same will be recorded in the minutes.

(l) Where there is conflict of interest, member will withdraw from the decision making procedure.

(m) In case of conditional approval of a proposal the same will be communicated to the investigators, with clear suggestions for modifications and Re-review procedure.

(n) Negative decision will be supported clearly by stated reasons.

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XI Policy on protection of vulnerable population:

(a) Research on genetics should not lead to promotion of racial inequalities.
(b) Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them;
(c) Rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders must be protected.
(d) Adequate justification is required for the involvement of subjects such as prisoners, students, subordinates, employees, service personnel etc., who have reduced autonomy as research subjects.

XII Policy regarding training for new and existing committee members along with SOPs

The Member Secretary of the Ethics committee collects the information on Drugs and Cosmetics rules, notifications and supplementary amendments from time to time and informs the committee members. Formal training in Good Clinical Practice along with certification will be organized by SBPIDSR at regular intervals.

XIII Procedure for communicating the decision of IEC to the applicant

The committee will give its opinion on the project in writing in one of the following ways;

Approval

Disapproval

Modification before approval

Discontinuation of previously approval project

The Chairman of the committee may provisionally approve without calling a full meeting in cases where only administrative amendment has been made. The Chairman will inform other members of the committee of the amendment and his decision. The decision will be ratified at the next full committee meeting and this will be minuted.

XIV Procedure for expedited review:

Only to be performed when there is no or minimum risk to the trial participants.

1) Re-examination of a proposal already examined by the IEC.
2) Study of minor nature eg., examination of case records.
3) Similar study proposal for which IEC had already given approvals earlier.
4) An urgent proposal of national interest having minimum risk.
5) Proposals with minimum risk to be reviewed when it may not be possible to convene a main ethics committee meeting with quorum- as for example during natural disasters, lockdowns, epidemics etc

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All expedited approvals will be given in a meeting with quorum of at least 3 members (nominated by the Chairman) of IEC. Quorum must have one expert or scientist having scientific knowledge in the field of proposal. It should also include either the Member Secretary or the Chairman or both.
Decision taken by the committee on expedited approval however will be brought to the notice of the main committee members for ratification.

XV Elements of Review:

Following are the elements to be reviewed by the IEC member.

A. Scientific design and conduct of the study:

1) The appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants.

2) The appropriateness of clinical trial site in terms of facilities to conduct the intended research and to take clinical care of the patients as per their requirements. This shall include investigations, treatment facilities, supportive staff follow-up facilities etc.

3) The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.

4) The justification for the use of control arms.

5) Criteria for prematurely withdrawing the research participants

6) Criteria for suspending or terminating the research as a whole

7) The adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a data and safety monitoring committee (DSMC).

8) The manner in which the results of the research will be reported and published.

B. Requirement of research participants:

1. The characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status and ethnicity).
2. The means by which initial contact and recruitment is to be conducted.
3. The means by which full information is to be conveyed to potential research participants or their representatives.
4. Inclusion criteria for research participants.
5. Exclusion criteria for research participants.

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C. Care and protection of research participants:

1. Any plans to withdraw or withhold standard therapies for the purpose of the justification for such action;
2. The medical care to be provided to research participants during and after the course of the research;
3. The adequacy of medical supervision and psycho-social support for the research participants.
4. Steps to be taken if research participants voluntarily withdraw during the course of the research.
5. The criteria for extended access to the emergency use of and/or the compassionate use of study products.
6. The arrangements, if appropriate for informing the research participants general practitioner (family doctor), including procedures for seeking the participant's consent to do so.
7. A description of any plans to make the study product available to the research participants following the research.
8. A description of any financial costs to research participants.
9. The rewards and compensations for research participants (including money, services, and /or gifts.
10. The provisions for compensation/treatment in the case of the injury disability/ death of a research participant attributable to participation in the research.
11. The insurance and indemnity arrangements.
12. The ethics committee shall look into the details of the protocol for formation of a data and safety monitoring board. In the absence of any such provision in the protocol, the IEC may insist on the same prior to approval or recommend to the Principal SBPIDSR to constitute a DSMB for monitoring the trial.

D. Protection of research participant confidentiality:

1) A description of the persons who will have access to personal data of the of the research participants, including medical records and biological samples;
2) The measures taken to ensure the confidentiality and security of personal information concerning research participants.

E. Informed consent process:

1. A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent.
2. Consent form in English and local language (Telugu) in case of studies on human subjects will be reviewed.
3. The adequacy, completeness, and understandability of written and oral information to be given to the research participants and when appropriate, their legally acceptable representative(s).
4. Clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals.

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5. Assurances that research participants will receive information that becomes available during the course of the research relevant to their participation (including their rights, safety and well-being).
6. The provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.

F. Community considerations:

1) The impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn.
2) The steps taken to consult with the concerned communities during the course of designing the research.
3) The influence of the community on the consent of individuals.
4) Proposed community consultation during the course of the research.
5) The extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research and the ability to respond to public health needs.
6) A description of the availability and affordability of any successful study product to the concerned communities following the research.
7) The manner in which the results of the research will be made available to the research participants and the concerned communities.

G. Selection of special groups as Research Subjects

i) **Pregnant or nursing women:** Pregnant or nursing women should in no circumstances be the subject of any research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about the foetus, pregnancy and lactation. As a general rule, pregnant or nursing women should not be subjects of any clinical trial except such trials as are designed to protect or advance the health of pregnant or nursing women or fetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable subjects.

a. The justification of participation of these women in clinical trials would be that they should not be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits. Example of such trials are, to test the efficacy and safety of a drug for reducing perinatal transmission of HIV infection from mother to child, trials for detecting fetal abnormalities and for conditions associated with or aggravated by pregnancy etc. Women should not be encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breast feeding to the nursing child should be properly assessed except in those studies where breast feeding is harmful to the infant.

b. Research related to termination of pregnancy: Pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could be made subjects for such research as per The Medical Termination of Pregnancy Act, GOI, 1971.

c. Research related to pre-natal diagnostic techniques: In pregnant women such research should be limited to detect the foetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the foetus.

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ii) Children: Before undertaking trial in children the investigator must ensure that –

a. children will not be involved in research that could be carried out equally well with adults;
b. the purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug the study in children should always be carried out after the phase III clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of the children;
c. a parent or legal guardian of each child has given proxy consent;
d. the assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors, adolescents etc.;
e. research should be conducted in settings in which the child and parent can obtain adequate medical and psychological support;
f. Interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child subject must be justified in relation to anticipated risks involved in the study and anticipated benefits to society;
g. the child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/ tested, provided the consent has been obtained from parents / guardian;
h. interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child subject as any available alternative interventions;
i. the risk presented by interventions not intended to benefit the individual child subject is low when compared to the importance of the knowledge that is to be gained.

H) **Appropriateness of investigator:** The ethics committee shall review the CV of the investigator, including qualifications, current designation and experience to determine whether he / she has appropriate capability to undertake the research in question (including clinical trials).

XVI Follow up procedure:

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 intervals of at least once in 6 months. But in a special situations, IEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.
3) The committee shall seek from the investigators:

- A progress report on six monthly basis or more frequently as the committee feels it.
- A report of each serious event when observed during the conduct of the study.
- To be kept informed of amendments to any study-related documents.
- To be kept informed of study discontinuation with reasons.

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4) With regard to Clinical trials, Data Safety Monitoring Board (DSMB) will be constituted by the Principal SBPIDSR or by the trial investigators to review the clinical trial notifications and to report the adverse events if any to the Institutional Ethics Committee. The board will review the clinical trial records for serious adverse events and report periodically to the IEC. Also the investigators have to communicate the observations of DSMB to IEC periodically.

5) All the requirements and procedures for follow up review will be similar to that of initial and main review. Following instances and events will require the follow-up review

   i) Protocol amendment, likely to affect, rights, safety or well being of research subject in conduct of study.
   ii) Serious or unexpected adverse reaction related to study or product, action taken by investigator, sponsor and regulatory authority.
   iii) Any event or information that may affect the benefit/risk ratio of the study.

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

IEC will also require the investigators to inform the committee about any SAE and payment of any compensation for the same. It shall also review the adequacy of treatment given to participants following an SAE.

In case of premature suspension/termination, the applicant must notify the IEC of the reasons for suspension/termination with a summary of results.

Applicant must inform at 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.

XVII Procedure for documentation and archiving:

1. All the documents and communications of IEC will be dated, filed and archived in a secured place.
2. Only the person, who is 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 of the study.
4. No documents (except agenda) will be retained by any IEC member.
5. At the end of each meeting every member will return all the research proposal documents to IEC office staff.

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XVIII Review of Performance of Ethics Committee:

The Principal cum Vice Chancellor of SBPIDSR who is the constituting authority of the IEC shall periodically assess the performance of IEC members in consultation with the Chairperson and Member secretary of the IEC, in terms of attendance, punctuality, participation in discussion and willingness to learn. The member secretary shall evaluate performance of the IEC itself in terms of time interval between submission of proposal and approval/rejection, maintenance of records, arrangements for meetings etc and shall carry out corrective action. Records shall be maintained of the review and any corrective and preventive action.

XIX Amendment of SOP:

Guidelines in this document may be subjected to amendments as and when the need arises. The faculty/investigators from SBPIDSR, or any other concerned citizen from public can suggest the need to add/delete, alter/amend certain clauses in this document. The SBPIDSR Ethics Committee or a special committee constituted for that purpose shall discuss the suggestions made before recommending for the same or otherwise. Member secretary will be responsible for tabling the amendments. Amended version of the document will be put before the Executive Board of SBPIDSR for its consideration and approval.

XX. Plagiarism

Plagiarism to be checked by plagiarism checking software Duplichecker and to be accepted if within 8%

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APPENDIX- I

UNDERTAKING FROM PRINCIPAL INVESTIGATOR

Ref No: Date:

Name and

Address of the Investigator (from SBPIDSR)

Chairperson/Member Secretary,

SBPIDSR Ethics Committee

S B Patil Institute for Dental Sciences

& Research, Bidar.

Sub: Ethical clearance for research project entitled "_____

_____"

UNDERTAKING

With respect to the above said research/clinical trial/thesis (strike off whichever is not relevant) protocol involving human subjects for which the ethical clearance being sought, I am to state that I have gone through SBPIDSR Ethical Committee Guidelines and am aware of the rules governing the studies involving the human subjects. I am also aware that these guidelines are strictly to be followed while carrying out the above said research project involving human subjects.

Further, I also affirm that I will be responsible to keep the IEC informed of,

i Any serious and unexpected adverse events and remedial steps taken totackle them.

ii Any new information that may influence the conduct of the study.

iii Any changes made in the consent form.

iv Under no circumstances I/we deviate from the original approval protocol without prior consent to that effect from the IEC. In the event of need to amend the original protocol approved by the EC, the proposed amendment shall be brought to the notice of EC for its consideration and approval.

Date: Name and Signature of the Principal Investigator

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APPENDIX- II

SPECIMEN CONSENT FORM

Information to the participants:

This section should contain the information about the diagnosis made, if any, and also about the various modes of treatments available, Subject needs to be given the free choice of selection of the treatments that are available, including the one which is being considered for the research study. Even if there is scope for slightest risk involved in the proposed mode of treatment/procedure, the same needs to be clearly informed to the participant and/or guardian of the person participating in the study. Participant in the proposed study be clearly informed about his/her right to withdraw from the study without any reason, if he/she desire so, and that would not affect in any way his/her treatment or of his/her ward/relative who is undergoing the treatment. Details regarding the scope of treatment in terms of duration, medications/procedures to be used and the clinical materials such as blood etc. that needs to be collected in terms of volume and periodicity be clearly stated in the information to be provided to the participant and/or the guardian. With this information made available to the participant in a language understandable to him/her, it needs to be followed by with the request and assurance, as enumerated below, from the investigator. i.e.,

Undertaking by the investigator:

Your consent to participate in the above study is sought. You have the right to refuse consent or withdraw the same during any part of the study without giving any reason. In such an event, you will still receive best possible alternative treatment, without any prejudice. If you have any doubts about the study, please feel free to clarify the same. Even during the study, you are free to contact any of the investigators for clarification if you so desire (investigators Name with Telephone No. need to be furnished). **All the information/data collected from you will be kept in strict confidence.**

Date: **Name & Signature of Principal Investigator**

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(Karnataka)

CHAIRPERSON
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Research Institute Ethics Committee
(SBPIDSR-IEC)
BIDAR-585 402, (Karnataka)

Consent:

I have been informed about the procedures of the study. The possible risks too have been explained to me as stated in the information. I have understood that I have the right to refuse my consent or withdraw it any time during the study without adversely affecting my/my ward's treatment. I am aware that by subjecting to this investigation, I will have to give more time for assessments by the investigating team and that these assessments do not interfere with the benefits.

I,……., the undersigned, give my consent to be a participant of this investigation/study program/clinical trial, entitled" _____

_____"

Signature of patient	Signature of the witness:	Signature of the investigator:
Name of patient	Name of the witness:	Name of the investigator:
Place	Place	Place
Date:	Date:	Date:

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Pl. note: (1) The above format is only a guideline, which may need to be altered according to the situation as to whether the participant is a patient, or patient's guardian or a volunteer who may take part in studies involving the study of normal subjects. Further, where the participant is not proficient with English, he/she be provided with a consent form in a language in which he/she is proficient.

(2) Informed Consent Form in minimum 3 languages viz. English, Hindi, Telugu and other languages where needed required to be furnished.

(3) Suppose the study group deals with only English or any particular language speaking patients, then an undertaking required to be furnished.

(4) A certificate from the translator stating that "the translated version of the informed consent form is the 'true' translation of the original version of the informed consent form" is required to be typed/printed at the end of the each translated version of the document. Further, the translator has to append his signature, name and address below the certificate.

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APPENDIX- III

IEC Membership Acceptance:

To

The Principal
S B Patil Institute for Dental Sciences and
Research, Bidar.

Sub: Consent to be a member of Institutional Ethics Committee.

******

Sir,

I accept the invitation to become a member of IEC of Sri Venkateswara Institute of Medical Sciences, Bidar. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues.

- I shall be willing to publicize my full name, profession and affiliation
- I shall make available to the public on request, all reimbursement for work and expenses if any related to IEC.
- I shall not keep any literature or study related document with me after the discussion and final review.
- I shall maintain the confidentiality regarding IEC activities.

I herewith enclose my CV.

Thanking you,

Yours sincerely,

Signature _____

Name of Member_____ Date_____

Address

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(Karnataka)

APPENDIX- IV

Application for Ethical Review of Biomedical Research Proposal

To
The Chairman
Institutional Ethics Committee
S B Patil Institute for Dental Sciences and
Research, Bidar

Date:

Full name of applicant: Designation:

Complete Address:

Tel.No

Fax No:

E-mail:

Site of Study:

Protocol No.(if any) Date:

Amendment No. Date:

Title of Project:

Type of study:

Local/National/International Type of

Trial : single center / multi centre

Sponsor's Name:

Address :

	Name	Signature
Principal Investigator :		
Co-Investigator: 1)		
2)		
3)		

(Application must be submitted along with all essential documents for the review)

(See list of Documents)

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BIDAR-585 402, (Karnataka)

PRINCIPAL
S.B. Patil Institute for
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NAUBAD, BIDAR-585402
(Karnataka)

List of documents to be submitted along with application for the IEC Review:

1. Signed and dated application form on prescribed format.
2. The protocol of the proposed research (clearly identified and dated), together with supporting documents and annexes.
3. A summary (as far as possible in non-technical language), synopsis, or diagrammatic representation (flowchart) of the protocol.
4. A description (usually included in the protocol) of the ethical considerations involved in the research.
5. Case report forms, diary cards and other questionnaires intended for research participants.
6. In case the research involves a study product (such as a pharmaceutical or device under investigation), an adequate summary of all safety, pharmacological, pharmaceutical and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g.: recent investigator's brochure published data, a summary of the product's characteristics); (Product information).
7. Investigator(s) curriculum vitae (update, signed and dated).
8. Material to be used (including advertisements) for the requirement of potential research participants.
9. A description of the process to be used to obtain and document consent.
10. Written and other forms of information for potential research participants (clearly identified and dated) in the language(s) understood by the potential research participants and, when required, in other languages.
11. Informed consent form (clearly identified and dated) in the language(s) understood by the potential research participants and when required in other languages.
12. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants.
13. A description of the arrangements for indemnity, if applicable.
14. A description of the arrangements for insurance coverage for research participants, if applicable.
15. A statement of agreement to comply with ethical principles set out in relevant guidelines.
16. All previous IEC's decisions (e.g., those leading to a negative decision or modified protocol) and by other regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on that account. The reasons for previous negative decisions must be provided.

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APPENDIX- V

Institutional Ethics Committee

S B Patil Institute for Dental Sciences and Research (SBPIDSR), BidarAcknowledgement

Date:

Received_____Copies of study proposal.

Protocol No._____ Dated:

Amendment No. Dated:

Entitled:_____

_____

From Dr._____

Designation_____

Address_____

For ethical review.

For official use only

* Study Proposal Registration No.SBPIDSR-IEC/200 /

* Name of IEC Staff * Signature

Receiving application:

* Date:

(To be filled by the applicant in duplicate)

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APPENDIX- VI

Institutional Ethics Committee

S B Patil Institute for Dental Sciences and Research (SBPIDSR), Bidar

Review letter No. IEC/SBPIDSR/ Date:

To

Ethics Committee of S B Patil Institute for Dental Sciences and Research (SBPIDSR), Bidar, in its Meeting held on_____at_____hours in the meetingroom_____reviewed and discussed the study proposed with Protocol No._____Dated__

Entitled"_____

_____

_____

Submitted by Dr._____.

Members:

Name	**Affiliation**	**Gender**
1.		
2.		
3.		
4.		
5..		

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Members reviewed the following documents (tick whichever is applicable):

1. Protocol ( )
2. Amendment ( )
3. Written informed consent ( )
4. Investigator's Brochure ( )
5. Available safety information ( )
6. Subject recruitment procedure ( )
7. Payments and compensation to subject ( )
8. Subject information sheet ( )
9. Investigator's C.V. ( )
10. Others: Specify_____( )

The members present, represented the quorum and having atleast one medically qualified person and atleast one layperson present from outside the Institute.

All the issues presented in the study proposal were thoroughly discussed and reviewed.

Of members present,_____voted for approval,_____ voted against and _____were absent.

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After all considerations, the committee has decided to approve / not to approve / suggested resubmission after required modification / subject to .

Please provide the following clarifications / documents for re-review.

1.

2.

3.

4.

The present approval is valid only for one year, investigator must take the re- approval after one year.

The investigator is requested to submit the progress report after 6 months to IEC for review. Any change, modification or deviation in the protocol, or any adverse event must be informed to ethics committee. Any protocol modification or amendment must receive IEC approval. Investigator should conduct the study as per the recommended GCP guidelines.

Signature :

Date :

Name :

Chairman

Institutional Ethics Committee

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APPENDIX- VII

S B PATIL INSTITUTE FOR DENTAL SCIENCES AND RESEARCH (SBPIDSR), BIDARPROFORMA TO BE FILLED BY THE PRINCIPAL INVESTIGATORS SUBMITTING RESEARCH PROPOSALS THROUGH SBPIDSR FOR CONSIDERATION OF THE ETHICAL COMMITTEE

TITLE OF THE PROJECT:_____

_____

PRINCIPAL INVESTIGATOR _____

DESIGNATION & DEPTT._____

PART – I

(In vivo experiments on human subjects)

1. Whether the human subjects are

Children (less than 15 years)	Yes/No
Elderly (More than 60 years)	Yes/No
Disabled (mentally or physically handicapped)	Yes/No
Prisoners/Restitutes	Yes/No

2. Whether the human subjects are

Suffering from illness	Yes/No
Normal individuals	Yes/No

3. Whether the project involves

Clinical trial with new drug(s)/ device(s) approved by DCI	Yes/No
Clinical trial with existing drug(s)/device(s) approved by DCI	Yes/No
Clinical trial with traditional medicines from Ayurvedic/Unani/Homoeopathy/Tribalsystems	Yes/No
None of the above	Yes/No

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(CAUTION: NO DRUG/DEVICE IS TO BE USED UNLESS APPROVED BY DRUG CONTROLLER OF INDIA)

If answer to 3.1 is yes, kindly furnish evidence of experimental and clinical safety of the drug (Use separate sheets)

4. Whether the project involves

Any invasive procedure which would otherwise not be performed for the management of the patient Yes/No

Use of invivo radioactive material Yes/No

Use of radiation Yes/No

If answer to any of 4.1 or 4.2 or 4.3 is yes then answer 5, below.

5. Do you think that the procedural risk or the cumulative risk of exposure is below safety limits Yes/No

PART – II

(COLLECTION OF HUMAN MATERIAL OTHER THAN NORMALLY EXCRETED URINE, STOOL, SALIVA, SWEAT, WHICH WOULD OTHERWISE NOT BE COLLECTED FOR THE MANAGEMENT OF THE PATIENT)

6. If the human material to be collected is human tissue specify the tissue

(.....)

It will be obtained by Operation/Biopsy/Abortion/Autopsy

Other (Specify_____)

Whether the procedure required to obtain the tissue is otherwise indicated for the management of the patient Yes/No

If answer to 6.2 is yes please explain the full procedure and justify collection and use of material (Use separate sheets)

7. Any other human material (Specify)

Yes/No If answer to 7 is yes then answer 7.1 and 7.2 below

Specify the method of collection(_____)

Specify the amount to be collected (_____)

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PART – III (COLLECTION OF BLOOD)

8. Will it be collected in amounts in excess of which would otherwise be collected for the management of patients Yes/No

if answer to 8 is yes then specify the excess amount

_____ ml at a time

_____ ml total

Will it be collected by extra peripheral venous puncture which would otherwise be required for the management of the patient Yes/No

If answer to 8.1 is yes then specify the total number of peripheral venous punctures (_____)

Will it be collected by a method which would otherwise not be required for the management of the patient ? Yes/No

If answer to 8.2 is yes then specify the method (_____)

PART – IV

(DECLARATION BY THE PRINCIPAL INVESTIGATOR)

9. I hereby declare that, Voluntary written informed consent of the human subject will be obtained.

In case of children and mentally handicapped subjects-voluntary written informed consent of the parents/guardians will be obtained.

The probable risk involved in the project will be explained in full details to the subjects/parents/guardians.

Subjects/parent/guardians will be at liberty to opt out of the project at any time.

I will terminate the experiment at any stage, if I have probable cause to believe, in the exercise of the good faith, skill and careful judgment required for me that continuation of the experiment is likely to result in injury, disability of death to the experimental subject.

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PRINCIPAL INVESTIGATOR

DEPTT._____

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PART – V

(DECLARATION BY THE PRINCIPAL INVESTIGATOR/HEAD OF THE DEPTT.)

1. Is the Dept./Institution ready to undertake the responsibility of the human subjects in case of injury Yes/No

   If yes, then will it include

   *Transportation charges Yes/No

   *Hospitalization charges Yes/No

2. Do you think that the experiments are so designed that they would yield meaningful results that could not be obtained by other methods.

   Yes/No

3. Do you think that the animal experiments carried out support the need for clinical experimentation Yes/No

4. Do you think that the experiments would be conducted in a manner to avoid all unnecessary physical and mental suffering and injury.

   Yes/No

5. Do you think the experiments have been planned in a manner so that the degree of risk to be taken would never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

   Yes/No

6. Do you think that proper preparations would be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death. Yes/No

7. Do you think that safeguards have been taken to see that the experimentation would be conducted only by scientifically qualified persons who possess the requisite competence, experience and qualities to carry out the research

   Yes/No

PRINCIPAL INVESTIGATOR_____

HEAD OF THE DEPTT._____

For drug trials the following are necessary before implementation;

1. Permission from DCG (I).
2. Memorandum of Understanding on Rs.100 Stamp paper (format given).
3. Indemnity agreement on Rs.100 Stamp paper (format given).

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APPENDIX- VIII

MEMORANDUM OF UNDERSTANDING

This Memorandum of understanding, (hereinafter called MoU) between S B Patil Institute for Dental Sciences and Research (SBPIDSR), Bidar, India (herein after called SBPIDSR) and (the Second Party) _____

_____(here after called_____

_____) entered into this_____

(day)_____(month) _____(year). Preamble:

Whereas SBPIDSR is a dental college and hospital, established by Somnath Education trust, as a centre of excellence for providing dental care, education and research of high order and is chartered to function as a university under this State Act.

Whereas (the Second Party)

Where as SBPIDSR and (the Second Party)_____

are willing to jointly participate in the development of_____

The coordinator of the project will be_____(name, designation of the faculty member responsible from SBPIDSR, Bidar).

The other Coordinator of the project will be_____(name, and designation of person responsible for second party).

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BIDAR-585 402, (Karnataka)

Scope of MoU

This MoU will cover the joint efforts of S B Patil Institute for Dental Sciences and Research (SBPIDSR), Bidar, and ____(Second Party) in
the area of_____

_____

(specify the area of work jointly to be done)

Furnish full details of the work to be done:

1.

2.

3.

4.

5.

Responsibilities of SBPIDSR:

1

2.

3.

4.

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Responsibilities of Second Party

1.

2.

3.

4.

5.

Administration:

Overall responsibilities of the project will rest with S B Patil Institute for Dental Sciences and Research (SBPIDSR), Bidar &

_____

(identify the Institution/Organization and name of the persons)

Financial Arrangements:

Funds for the projects will be from_____(name the funding agency) and the proportion of the funds to be released to SBPIDSR will be Rs.____(specify the amount).

The following equipment/consumables/supplies will be provided to SBPIDSRby (Second Party)._____

(This is for MoU involving grant of

equipment/consumables/supplies)

1.

2.

3.

4.

5.

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Intellectual Property Rights:

1. The R&D information generated shall be shared by both the collaborating parties.
2. Any publication shall be by mutual consent of the coordinators.
3. Patents and other benefits, arising out of the project if any, shall be shared between the collaborating parties.
4. For projects identified as having a distinct potential of generating know how leading to commercial applications *NRDC (National Research Development Corporation of India) Guidelines will be followed.

NRDC GUIDELINES

1. To bring to the notice of the Investigator, prospective user of the technology being developed.
2. To do market research about the product and bring out a comprehensive study about the market potential for attending entrepreneur.
3. For effective coordination between the laboratory generating the know how and the entrepreneur.
4. To take such other steps as may facilitate the communication of know how.
5. NRDC will retain 40% of the royalty/premia and the remaining 60% will be sent to the Institution generating the know how. The sharing of 40% between the Institute and the project investigator team may be decided by the Institute.

Duration of MOU

This MoU will be in force for a period of_____(Years) from the date of its signing).

Amendments to the MoU

Amendments if any, before the expiry of this MoU shall be made in writing by the Authorized representatives of SBPIDSR and_____(second party) after mutual agreement.

Resolution of Dispute:

Any dispute or difference between the collaboration parties shall be amicably resolved by either through mutual consultation or arbitration.

Seal of the Parties:

In witness thereof Parties hereto having signed this MoU on the day, month and year mentioned herein before.

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(SBPIDSR-IEC)
BIDAR-585 402. (Karnataka)

Parties:

Signed and delivered for and behalf of SBPIDSR	Signed and delivered for and behalf of (Second Party)
Signature	Signature
Name	Name
Designation	Designation
Seal	Seal

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APPENDIX- IX

INDEMNITY AGREEMENT

This indemnity agreement is between S B Patil Institute for Dental Sciences and Research (SBPIDSR), Bidar, India (hereinafter SBPIDSR) and _____

_____

(Name of the second party/ sponsor)

(hereinafter SPONSOR)

Whereas SBPIDSR engages in medical research that involves experimental and investigational products, drugs, devices or therapy and

Whereas SPONSOR owns or has right to such experimental or investigational products, drugs, devices specifically as it relates to this agreement, products, devices, drugs shall mean the following.

1.

2.

3.

4.

5.

Whereas SBPIDSR and SPONSOR have agreed that SBPIDSR will use SPONSOR'S experimentaland investigational products, drugs, devices for research purpose.

Now therefore, the parties agree as follows:

1. **Undesirable side effects, injuries, illness or reactions.**

   The SPONSOR agrees to indemnify, protect, defend and hold harmless SBPIDSR, its officers, employees against cost or expenses associated with the diagnosis and treatment of undesirable side effects, injuries, illness or reactions that arise specifically from SPONSOR's products, devices, drugs.

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2. **Loss, Damage or Liability.**

The SPONSOR agrees to indemnify, protect, defend and hold harmless SBPIDSR, its officers, employees from any loss, damage or liability they may suffer or incur as a result of claim or demands made against them that arise specifically from research involving SPONSOR's products, devices, drugs.

3. **Insurance**

The SPONSOR agrees to maintain in force at its sole cost and expense with reputable insurance companies, Insurance of a type and in amounts equal to at least_____per

(specify the amount of money)

occurrence combined single limit and_____annual

(specify the amount of money)

SBPIDSR shall have the right to request the appropriate certificates of insurance from SPONSOR for purposes of ascertaining the sufficiency of coverage.

4. **Attorneys and legal coverage.**

The SPONSOR agrees to provide, at its own expenses, attorneys to defend against any claims made or action filed against SBPIDSR, its officers, employees. The SPONSOR also agrees to pay any settlement amounts or judgments levied against SBPIDSR or any losses or expenses incurred by SBPIDSR resulting from such claims or action.

5. **Cooperation of parties.**

SBPIDSR agrees to notify promptly, SPONSOR in writing when any undesirable side effect, injury, illness or reaction arises from research involving SPONSOR's products, devices, drugs, SBPIDSR agrees to cooperate with SPONSOR in defending any claim or action covered by this agreement. The SPONSOR agrees to consult on a regular basis with SBPIDSR regarding the defense or settlement of any claim or action. Neither party will compromise or settle any claim or action without prior written consent of the other party.

6. **Other.**

This indemnity agreement does not displace, supercede or in any way limit any other agreements between the parties.

SBPIDSR

Name_____

Signature_____

Date_____

Seal_____

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CHAIRPERSON
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Research-Institute Ethics Coommittee
(SBPIDSR-IEC)
BIDAR-585 402, (Karnataka)

REFERENCES

1. Ethics Committee guidelines of AIIMS, New Delhi.
2. Ethics Committee guidelines of SGPGIMS, Lucknow.
3. Ethics Committee guidelines of NIMHANS, Bangalore.
4. Ethics Committee guidelines of NIMS, Hyderabad.
5. Ethics Committee guidelines of CMC & Hospital, Vellore.
6. Ethical guidelines of ICMR, New Delhi.
7. Rajiv Gandhi University of Health Sciences, Karnataka

i) Undertaking Form by Principal Investigator - NIMHANS, Bangalore
ii) Specimen consent form - -do-
iii) IEC Membership Acceptance Form - NIMS, Hyderabad
iv) Application for Ethical Review Biomedical Research Proposal - -do-
v) List of documents to be submitted - -do-
vi) IEC acknowledgement Form -do-
vii) IEC Review Letter - -do-
viii) Proforma to be filled by the Principal Investigator - SGPGIMS, Lucknow
ix) MOU for drug trials -do-
x) Indemnity agreement for drug trials- -do-

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