Document No.: BJS/IEC/SOP-A12022/1/39

Standard Operating Procedures For Institutional Ethics Committee

B.J.S Dental College & Hospital
Ludhiana (Punjab), India

Date of Amendment: 18.01.2022
Effective Date: 19.01.2022

Prepared By:	Reviewed By:	Approved By:
Dr. Sunaina Jodhka	Dr. Roopinder Kaur	Dr. Ashutosh Nirola
(Member Secretary)	(Pharmacologist)	(Chairperson)

STANDARD OPERATING PROCEDURE (SOP) OF INSTITUTIONAL ETHICS COMMITTEE OF BABA JASWANT SINGH COLLEGE HOSPITAL AND RESEARCH INSTITUTE

The following may be called as "Standard Operating Procedures for the Institutional Ethics Committee (IEC) of B.J.S. Dental College and Hospital, Ludhiana. This is a dynamic document which will be reviewed periodically and changes incorporated as per ICMR and New Drugs and Clinical Trials guidelines and institutional policies.

Purpose of IEC:

The need for IEC is to ensure that a competent body exists to review the scientific and ethical aspect 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 participants.

Scope of IEC:

This procedure covers a competent review of research project proposals in human subjects and/or patients.

- Research projects undertaken by the personnel of B.J.S. Dental College and Hospital. No outside projects will be considered.
- No fee will be charged for reviewing the projects for ethical clearance.
- The type of projects will include in-vitro/ in-vivo studies of all approved materials or molecules.
- No unapproved / new drug molecule or drug trial will be conducted on study participants.
- To safeguard the dignity, rights, wellbeing of research participants, IEC will review research proposals prior to their initiation and monitor the approved research to ensure compliance at timely intervals.

Role and Responsibilities of IEC.

The IEC will review research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of all research participants before approving the research proposals.

The 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 upheld.

The institution is responsible for providing logistical support (infrastructure, staff, space, funds and time) to run IEC.

IEC 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.

The mandate of the IEC shall be to review all research projects to be conducted in 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.

In case 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.

In case of serious adverse events the information would be duly forwarded to the nodal centre. It would be the responsibility of the principal investigator to bring it to the notice of the IEC.

Authority under which the ethics committee has been constituted (Authority letter from authorized person of hospital/Institute)

The Principal will appoint the Chairperson and all the committee members based on their competence, experience and integrity, by request (Prototype letter attached as Annexure-2A).

Members will confirm their acceptance to the Principal, by providing all the required information for membership (Prototype letter attached as Annexure-2B).

The Chairperson will furnish any information or report to the Principal, when required.

S.No 2 (14)

Baba Jaswant Singh Dental College, Hospital & Research Institute
Chandigarh Road, Ludhiana 141 010, Punjab (India) Phone: 0161–5055162, 5055163
Fax: 0161 – 2677326 E-mail: bjsdental@rediffmail.com

BJSDC/4447
Dated: 20.07.2022

To,

The Head,
Department of Health Research
[National Ethics Committee Registry
for Biomedical and Health Research],
2nd Floor, IRCS Building, Red Cross Road,
New Delhi – 110001

Subject: Reg. registration of IEC of B.J.S. Dental College, Hospital & Research Institution, Ludhiana

Dear Sir,

I, Dr. Harpreet Singh have joined as Principal, B.J.S. Dental College, Hospital & Research Institute w.e.f. 18-05-2022 and further state that the modified Institutional Ethics Committee of B.J.S. Dental College, Hospital & Research Institute has been constituted under my authority w.e.f. 01-06-2022.

The members have been appointed based on their experience, competence and integrity by request and mutual consent.

The Institutional Ethics Committee will function independently and according to the New Drugs and Clinical Trials rules, 2019 and ICMR ethical guidelines 2017 (as amended from time to time).

The Principal shall be an appellate authority and ensure the provision of infrastructure, administration and financial support, as required for smooth functioning of Institutional Ethics Committee.

This is for your kind information and perusal.

Prof (Dr.) Harpreet Singh
Principal

Principal
B. Jaswant Singh Dental College
Hospital & Research Institute, Ludhiana

S.No 2(2/2)

Baba Jaswant Singh Dental College, Hospital & Research Institute
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BJSDC/ 2964 Dated: 01-06-2022

To

The Chairperson &
Members of Institutional Ethics Committee (IEC) of
B.J.S. Dental College, Hospital & Res. Institute, Ludhiana

Dear Sir/Madam,

I am pleased to authorize the continuation of your services in the Institutional Ethics Committee (IEC) in the following capacities until the completion of your tenure, as per appointment letter issued of the beginning of your term.

Sr. No.	Name	Area	Affiliate / Non Affiliate
1	Dr. Ashutosh Nirula Principal & Professor, Periodontics Luxmi Bai Institute of Dental Sciences, Patiala	Chairperson	N.A.
2	Dr. Sunaina Jodhka, Professor, Dept. of Pedodontics, B.J.S. Dental College & Hospital, Ludhiana	Member Secretary	A
3	Dr. Saurabh Bither, Ex-Professor, Oral Surgery Luxmi Bai Institute of Dental Sciences, Patiala	Clinician	N.A.
4	Dr. Jaswinder Kaur, Professor, Dept. of Prosthodontics	Clinician	A
5	Dr. Roopinder Kaur Prof., Pharmacology B.J.S. Dental College & Hospital, Ludhiana	Pharmacologist	A
6	Dr. Ekta Singh Suneja Prof., Conservative Dentistry, B.J.S. Dental College & Hospital, Ludhiana	Clinician	A
7	Dr. Santosh Mahajan Prof, Biochemistry B.J.S. Dental College & Hospital, Ludhiana	Basic Medical Science	A
8	Mr. Jashandeep singh	Legal Expert	NA
9	Mr. Iqbal Singh	Phillosopher/Ethicist/Theologian	NA
10	Mr. Darshan Singh	Social Worker / Representative of NGO	A
11	Mr. Paramjit Singh	Lay Person from the community	NA

Prof. Dr. Harpreet Singh
Principal

Principal
Baba Jaswant Singh Dental College
Hospital & Research Institute, Ludhiana.

Memberships requirements of the ethics committee

EC will be a multidisciplinary and multi-sectorial body in composition and independent. The number of members of the Review Board may range from 7 to 15. The chairperson/ Chairman 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 nonscientific persons and may also include members of public to reflect the different points of view.

There will be adequate representation of age and gender in the Committee to safeguard the interest and welfare of all sections of the society. Member shall 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 IEC will include

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

A sub-board/ subcommittee of the main IEC may be formed by the chairman of IEC to review research proposals (Synopsis) of Post-Graduate or Undergraduate students, similarly another subcommittee of the main IEC may be formed to review research proposals which necessitates expedite review. The chairperson, member secretary and one two appropriately designated members of main IEC, will be part of the sub-committee.

Role & Responsibilities of IEC Members

Chairperson (Non Affiliate Member)

- Conduct EC meetings and be accountable for independent and efficient functioning of the committee
- Ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations
- Ratify minutes of the previous meetings
- In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.
- Seek COI declaration from members and ensure quorum and fair decision making.
- Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.

Member Secretary (Affiliate Member)

- Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review
- Schedule EC meetings, prepare the agenda and minutes
- Organize EC documentation, communication and archiving
- Ensure training of EC members
- Ensure SOPs are updated as and when required
- Ensure adherence of EC functioning to the SOPs
- Prepare for and respond to audits and inspections
- Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.
- Assess the need for expedited review/ exemption from review or full review.
- Assess the need to obtain prior scientific review,
- Invite independent consultant, patient or community representatives.
- Ensure quorum during the meeting and record discussions and decisions.

Basic Medical Scientist(s) (Affiliated/ non-affiliated)

- Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report
- Pharmacologist to review the drug safety and pharmacodynamics.

Clinician(s) (Affiliated/ non-affiliated)

- Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics
- Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report)
- Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation.
- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

Legal Expert/s (Affiliated/ non-affiliated)

- Ethical review of the proposal, ICD (inform consent document) along with translations, insurance document if any, researcher's undertaking, protocol specific other permissions, MoU for international collaboration, compliance with guidelines etc.
- Interpret and inform EC members about new regulations if any

Social scientist/ philosopher/ ethicist/theologian (Affiliated/ non-affiliated)

- Ethical review of the proposal, ICD along with the translations.
- Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any
- Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.

Lay person(s) (Non-affiliated)

- Ethical review of the proposal, ICD along with translation(s).
- Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.
- Serve as a patient/participant/ community representative and bring in ethical and societal concerns.
- Assess on societal aspects if any.

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, Principal of the Institute, in consultation with the Chairman of IEC, can disqualify any member, if the contribution is not adequate and/or there is long period of non-availability of the member.
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. Principal of the Institute 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 -2B)
6. Conflict of interest should be declared by members of the IEC prior to review meeting.

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B.J.S. Dental College,

Hospital & Research Institute, Ludhiana

Dated: 01.06.2022

Office Order

Ethical Committee for the college has been re-constituted. Following are the members of this:

Sr. No.	Name	Role/Area	Affiliate / Non Affiliate
1	Dr. Ashutosh Nirula Principal & Professor, Periodontics Luxmi Bai Institute of Dental Sciences, Patiala	Chairperson	N.A.
2	Dr. Sunaina Jodhka, Professor, Dept. of Pedodontics, B.J.S. Dental College & Hospital, Ludhiana	Member Secretary	A
3	Dr. Saurabh Bither, Ex-Professor, Oral Surgery Luxmi Bai Institute of Dental Sciences, Patiala	Clinician	N.A.
4	Dr. Jaswinder Kaur, Professor, Dept. of Prosthodontics	Clinician	A
5	Dr. Roopinder Kaur Prof., Pharmacology B.J.S. Dental College & Hospital, Ludhiana	Pharmacologist	A
6	Dr. Ekta Singh Suneja Prof., Conservative Dentistry, B.J.S. Dental College & Hospital, Ludhiana	Clinician	A
7	Dr. Santosh Mahajan Prof, Biochemistry B.J.S. Dental College & Hospital, Ludhiana	Basic Medical Science	A
8	Mr. Jashandeep singh	Legal Expert	NA
9	Mr. Iqbal Singh	Phillosopher/Ethicist/Theologian	NA
10	Mr. Darshan Singh	Social Worker / Representative of NGO	NA
11	Mr. Paramjit Singh	Lay Person from the community	NA

Sunaina Jodhka

Prof. Dr. Harpreet Singh
Principal

Principal
Baba Jaswant Singh Dental College
Hospital & Research ... Ludhiana

Sunaina Jodhka

The terms of reference of the committee

Terms of reference and SOP will be maintained in the office of IEC.

Purpose of IEC:

The need for IEC is to ensure that a competent body exists to review the scientific and ethical aspect 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 participants.

Scope of IEC:

EC will function according to written SOP available in secretariat of IEC.

The type of projects taken up by IEC of B.J.S. Dental College is as follow;

- Research projects undertaken by the **personnel of B.J.S. Dental College and Hospital**.
- **No outside projects** will be considered.
- **No fee** will be charged for reviewing the projects for ethical clearance.
- The **type of projects** will include **in-vitro/ in-vivo studies** of all **approved** materials or molecules.
- No unapproved / new drug molecule or drug trial will be conducted on study participants.
- To safeguard the dignity, rights, wellbeing of research participants, IEC will review research proposals prior to their initiation and monitor the approved research to ensure compliance at timely intervals.

Composition of IEC:

- IEC will be established by the head of the institution.
- It will be multidisciplinary and multi-sectorial in composition having seven to fifteen members with a mix of medical, non-medical, scientific, non-scientific members including lay person/s from the community.
- It will be well represented in terms of gender, age and social background.

- The head of the institution will be responsible for appointing the committee members with mutual consent, based on their interest, scientific and ethical knowledge and their commitment and willingness to volunteer necessary time and effort for IEC work.
- The chairperson and the IEC members can suggest names of potential members but final decision will remain with the head of the institution.

Committee will comprise of:

1. **Chairperson** from outside the institution. A well-respected person from any background with prior experience of having served/ serving in an EC.
2. **Member Secretary** from within the institution having knowledge and experience in clinical research and ethics, be motivated and have good communication skills.
3. **Basic Medical Scientist(s)** Medical or Non-Medical person having qualification in basic medical sciences.
4. **Clinician** an individual with recognized medical qualifications, expertise and training.
5. **Legal Expert** should have basic degree in law from recognized university.
6. **Social scientist/ philosopher/ ethicist/theologian** individual with social, behavioral science, philosophy, religious qualification and training who is sensitive to cultural and moral values.
7. **Lay Person** a non-medical and non-health related individual who is literate and aware of local language cultural and moral values of the community.

Terms & Conditions of Appointment

- Members of the ethical committee reviewing scientific projects will have experience in research related activities (minimum of three years).
- Members will be trained in SOP and GCP guidelines.
- Members will be consent to giving adequate time for review of projects on ethical issues.
- Terms of appointment with reference to **duration of term** (refer to annexure 2A & 2 B)

SOP for appointment and the quorum required

Condition of Appointment:

1. Members of the Ethical Committee reviewing scientific projects will have experience in research related activities (minimum of three years).
2. They will be trained in SOP of the IEC and GCP guidelines (within six months of enrollment).
3. Members will consent to giving adequate time for reviewing projects on ethical issues.
4. No gratuity will be provided for the same.
5. Members will be willing to provide full name, CV, profession and affiliation.
6. A minimum of three years shall comprise terms for serving as a member.
7. Renewal shall be by mutual consent and one month notice will be necessary prior to resignation.
8. Members will declare conflict of interest, if any.

Quorum Requirement: The quorum will be as per guidelines for biomedical and health research as issued by ICMR from time to time.

1. Member secretary will ensure that a minimum of five members are present which will include both medical and non-medical members.
2. Minimum one non affiliate member will be a part of the quorum.
3. A lay person will also the part of the quorum.
4. Minimum one member from the opposite gender will be present.
5. No decision will be valid without the fulfilment of the quorum.
6. The full committee shall be present to give ethical clearance for study participants who fall under the vulnerable population category.

SOP for resignation, replacement or removal of members.

In case a member has to resign, the reason for resignation shall be submitted in writing through proper channel to the Chairman Ethics Committee and the decision shall be taken preferably unanimously by the members in the EC meeting.

The decision on replacement of the member will also be taken by the Ethics Committee after presenting relevant documents through Member Secretary.

In both cases, a month's notice will have to be provided by the EC member.

Documents, proving that the members of the committee are conversant with the provisions as specified in latest edition of National ethical guidelines for biomedical and health research involving human participants. (Copies of BIO Data & training certificates showing that all members are conversant with provisions of GCP and relevant guidelines, attached as annexures 7a, 7b and 7c.

Members will be trained in human research protection, EC functions and SOPs, and be conversant with ethical guidelines, GCP guidelines (if applicable) and relevant regulations of the country.

Every EC member must:

1. Provide a recent signed CV and training certificates on human research protection and Good clinical practice (GCP) guidelines, if applicable;
2. Either be trained in human research protection and/or GCP at the time of induction into the EC, or must undergo training and submit training certificates within one year of appointment (or as per institutional policy);
3. Be willing to undergo training or update their skills/knowledge during their tenure as an EC member;
4. Be aware of relevant guidelines and regulations and trained on SOPs;
5. Read, understand, accept and follow the conflict of interest, COI policy, of the EC and declare it, if applicable, at the appropriate time;
6. Sign a confidentiality and conflict of interest agreement
7. Be willing to place her/his full name, profession and affiliation to the EC in the public domain; and
8. Be committed and understanding to the need for research and for imparting protection to research participants in research.

All trainings will be documented. Any change in the relevant guidelines or regulatory requirements will be brought to the attention of all EC members.

EC members should be aware of local, social and cultural norms and emerging ethical issues.

SOP for updating and training of 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.

3. It is preferable to train the IEC members in Good Clinical Practice.

4. All members will be trained in human research protection of SOP of IEC of B.J.S. Dental College & Hospital and shall be appraised of the amendments, if any, as made from time to time.

5. This training will be done at initial and on regular intervals.

6. 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.

SOP for Conduct of IEC meetings

The Chairman will conduct all meetings of the IEC. In the absence of the Chairman, 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.

SOP for Procedure of the Meeting

1. Meeting will be called to order.
2. Minutes of the meeting will be approved
3. All proposals will be discussed in sequence.
4. The meeting of the IEC will be held at a convenient date and time.
5. All projects will first be approved by the Heads of the respective departments and will have administrative clearance for administrative assessment of justification, relevance and benefits to the institute, before being presented to the ethics committee.
6. 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.
7. Independent consultants/experts will be invited to offer their opinion on specific research proposals, if needed.

Decisions will be tried to be taken by mutual consent and after discussion, and whenever needed voting will be done. The decisions will be minuted and Chairperson's approval taken in writing.

SOP for Independent consultants

The IEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. 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 IEC.

SOP for Application procedures

1. All research proposals should be submitted on any working day, the details of which are given under "Documentation". Application of the research proposal along with relevant documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators/ Research Scholars shall be guided to the Chairperson-IEC, through member secretary. Receiving of the application will be acknowledged by the IEC office.
2. Every application will be allotted an IEC registration number. The date of IEC meeting will be intimated to the PI. PI shall attend the meeting; make a brief presentation of the proposal and to clarify the points raised by the members.
3. The decision of the committee on the proposal will be communicated in writing. If revision is to be made, the revised document and required number of copies should be submitted within a stipulated period of time as specified in the communication.

SOP for review of research proposal by IEC

1. Prior approval by appropriate scientific review committees / Research committee / Institutional Scientific Committee.
2. Procedure for selection of subjects including inclusion / exclusion.
3. Protection of privacy and confidentiality.
4. In case of clinical studies, Patient information sheet, informed consent form in English and in local languages.(refer to annexure 8D)
5. Statistical aspects of sample size, data analysis and reporting.
6. Examination of predictable risks and benefits.
7. Reporting of adverse events and their management.
8. Justification for placebo in control arm, if any.
9. Competence of investigators, research and supporting staff.
10. Facilities and infrastructure of study sites.
11. Evaluation in case of premature withdrawal of patients, suspension or premature termination of a study.
12. Adherence to all regulatory requirements and applicable guidelines.

Standard operating procedures to be followed by the committee for vulnerable population

1. 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 or mental illness.

   ICMR guidelines as applicable will be followed for protection of vulnerable population.
2. The full committee shall be present to give ethical clearance for study participants who fall under vulnerable population category.
3. Justification for inclusion / exclusion of vulnerable population.
4. Conflict of interest and risk benefit ratio will be assessed.
5. Ensure proper informed consent of patient/ parent/ guardian or LAR is taken.
6. Safeguards for regular review and monitoring of ongoing study in vulnerable population.

SOP of Policy regarding training for new and existing committee members

Committee members will be instructed to get themselves well versed with policies, guidelines and requirements for serving as member/ office bearer of Ethics Committee of the institution as per ICMR guidelines.

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.
3. It is preferable to train the IEC members in Good Clinical Practice.
4. New members will be trained in SOP of IEC of B.J.S. Dental College & Hospital and old members shall be appraised of the amendments, if any, as made from time to time.

SOP Policy to monitor or prevent the conflict of interest

All Principal Investigators will be required to submit a declaration, wherein, they will be instructed to state if they have any COI (conflict of interest) of financial or non-financial (personal, academic or political) nature.

The institution will not interfere with the decision making of IEC.

IEC will evaluate the study in light of disclosed COI and ensure appropriate action to mitigate it.

EC requires members to disclose their own conflict of interest and take appropriate steps to recuse themselves from reviewing or decision making of such protocols.

SOP for 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, but will not participate in decision making process.
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.
6. *Modified proposals will be reviewed by an expedited review* through identified IEC members.

If amendment to the study related document is purely administrative in nature, not involving any change in study design or safety criteria, it may be provisionally approved by the Chairperson or Member Secretary of the committee, without calling full meeting. The Member Secretary will then inform all other members of the IEC about the amendment.

SOP for Communicating the decision

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

2. The communication letters shall be collected by the PI from IEC office.

SOP for Documentation

All Research proposals -hard copies along with soft copy (covering letter, proposals, checklist etc in MS Word Format) along with the information and documents as specified in Annexures- 8A and 8B, shall be forwarded through the Head of the Department to IEC.

SOP for Record keeping and archiving at the office of 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 2 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 research proposals and documents to IEC office staff.
6. Following documents will be filed and archived with proper label on the top of file for easy identification

a. Constitution and composition of IEC
b. Curriculum Vitae (CV) of all members of IEC with records of training in Human ethics if any.
c. Standard Operating Procedures of IEC.
d. Annual reports
e. Copy of all study protocols with enclosed documents and progress reports.
f. Minutes of all IEC meetings duly signed by the Chairperson / Member secretary.
g. Final report of the approved projects.

All the documents related to research proposals will be archived for a minimum period of 2 years by the PI/Researcher, following the completion / termination of the study.

SOP FOR FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY INSTITUTIONAL ETHICS COMMITTEE OF BJS DENTAL COLLEGE, HOSPITAL & RESEARCH INSTITUTE

No research project shall be / can be started unless ethics clearance/approval is obtained.

All submissions should be made in the prescribed Format to the IEC with signatures of all the investigators.

Forward hard copies and a soft copy (in CD/DVD) of the Research Proposal along with Covering letter, through the Head of the Department with all the required information guided to Chairman IEC.

Project Submission Time:

Submissions will be made at least 15 days prior the scheduled Institution Ethics Committee meeting.

Meeting of institutional ethics committee will be held well in advance of the submission of research projects to BFUHS.

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.

Details need to be submitted for Initial Review for Research Proposal

1. Covering letter through proper channel (Head of the Department) addressed to Chairman IEC.
2. Title of the research proposal
3. Name of the Principal Investigator with qualification and designation.
4. Name of the Co-Investigator (s) with qualifications and designation
5. Name of the Institute/ Hospital/ Field area where research will be conducted
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, duration of treatment and details of invasive procedures if any, plan for statistical analysis of the study.
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. Source of funding and financial requirements for the project have to be detailed, if any.
8. Expected benefits to subjects/volunteers/community. Benefits to other categories, if any.
9. Agreement to report all Serious Adverse Events (SAE)/death to IEC.
10. Accountability for data collection and storage.
11. Agreement to comply with the relevant national and applicable international guidelines, ICMR guidelines, Good Clinical Practices (GCP) protocols for clinical studies.

12. Plans for publication of results / positive or negative / while maintaining the privacy and confidentiality of the study participants.
13. Statement of conflicts of interest, if any.
14. Usefulness of the project/trial
15. Undertaking to inform the completion of study (within 15 days of completion of the study) to IEC.
16. Any other information relevant to the study.
17. 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

Annexure-2A

APPOINTMENT ORDER

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

I am pleased to appoint you as.....of the Institutional Ethics Committee (IEC) at BJS Dental College, Hospital & Research Institute, Ludhiana w.e.f ..... for a term of.....year / months provided following conditions of appointment are met.

You should be willing to publicize your full name, profession & affiliation.

You are willing to record all expenses, if any, within or related to an EC & make it available on request.

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 consent & one month notice will be necessary prior to resignation of appointment. Terms & Conditions regarding the resignation procedure, disqualification procedures, replacement procedures etc. may be found in the Standard Operating Procedures (SOPs) of IEC, BJS Dental College, Hospital & Research Institute, Ludhiana.

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

Signature of Appointee

Principal

Annexure -2B

MEMBERSHIP CONSENT LETTER

From

.....

.....

.....

.....

To

The Principal,

BJS DENTAL COLLEGE & RESEARCH INSTITUTE,

LUDHIANA

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

Ref: Your Letter No: dated:

Dear Sir/ Madam,

In response to your letter stated above, I give my consent to become a member of IEC of BJS Dental College & Hospital, Ludhiana. 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 here with enclose my CV.

Thanking you,

Yours sincerely,

Signature

Date

Name:.....

Telephone Number.....

Email Address.....

Annexure-8A

Covering Letter for the study to be submitted for Institutional Ethical Clearance

(in non-running legible hand writing in blue ball pen only)

(Research proposal to be submitted as 1 Hard Copy & 1 Soft Copy)

Proposal Title:

.....

.....

.....

.....

.....

Serial No of IEC: _____

	Name, Designation, Department & Qualifications	Signature
PI		
Co-PI		
Co-PI		
Co-PI		

Annexure 8B

To be filled if the study is funded by a Sponsor (Tick appropriately)

Sponsor Information

1. Indian	a) Government ☐ b) Private ☐	Central ☐	State ☐	Institutional ☐
2. International	Government ☐	Private ☐	UN Agencies ☐	
3. Industry	National ☐		Multinational ☐	
Contact Address of Sponsor:				
Total Budget:				

Who will bear the cost of investigation/ implants drugs/ contrasts	1. Patient 2. Project 3. Exempted 2. 4. Other Agencies

1. Status of Review: New ☐ Revised ☐			
2. Type of Study: Cross Sectional ☐ Case Control ☐ Cohort Clinical ☐ Trial Review ☐ Participating Centre: Single Center ☐ Multi-centric ☐ Other (Specify).....			
3. Clinical Trials: Drug/ Vaccines/Device/ Herbal Remedies: i. Does the study involves use of: Drug ☐ Device ☐ Vaccine ☐ Indian Systems of Medicine/ alternate System of Medicine ☐ Any Other ☐			
ii. Is it approved and marketed in India ☐ UK & Europe ☐ USA ☐ Other Countries, Specify ☐			
iii. Does it involve a change in use, dosage, route of administration?		Yes	No
If yes whether DCGIs/Any other Regulatory authority's Permission is obtained?		Yes	No
If yes, Date of Permission:			
iv. Is it an investigational New Drug? If yes, IND No.		Yes	No
a) Investigators Brochure submitted		Yes	No
b) In vitro studies data		Yes	No
c) Preclinical Studies done		Yes	No
d) Clinical Study is: Phase I Phase II Phase III Phase IV			
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		
iv. Inclusion / exclusion criteria given		

v. Type of Subjects Volunteer ☐ Patient ☐

vi. Vulnerable subjects Yes ☐ No ☐
(Tick the appropriate boxes)

Pregnant Women	Children	Elderly	
Fetus	Illiterate	Handicapped	
Terminally ill	Seriously ill	Mentally ill	

vii. Special group subjects Yes ☐ No ☐
(Tick the appropriate boxes)

Captives	Institutionalized	Employees	
Students	Nurse/ Dependent	Armed	
Any Other	Staff	Forces	

6. Privacy and Confidentiality

i. Study Involves –

Direct Identifier ☐ Indirect Identifier/coded ☐ Completely Anonymised ☐

ii. Confidential handling of data by staff Yes ☐ No ☐

7. Use of biological/hazardous materials	Yes	No
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 r DNS 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 ionizing radiation/radioisotopes	Yes	No
	Yes	No
vii. Use of Infectious/bio hazardous specimens	Yes	No
viii. Proper disposal of material	Yes	No

ix. Will any sample collected from the patients be sent abroad? **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? b. Sample will be sent abroad because (Tick appropriate box): Facility not available in India Facility in India inaccessible Facility available but not being accessed. If so, reasons	Yes Yes	No No

8. **Consent :** *Written ☐ Oral ☐ Audio-visual ☐

i. Consent form : (tick the included elements)

Understandable language	Alternatives to participation
Statement that study involves research	Confidentiality
records Sponsor of study	Contact information
Purpose and procedures	Statement that consent is voluntary
Risks &Discomforts	Right to withdraw
Benefits	Consent for future use of biological
material Compensation for participation	Benefits if any on future commercialization
Compensation for study related injury	
*If written consent is not obtained, give reasons:	

ii. Who will obtain consent? PI/Co-PI Research staff

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? ii. Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk More than minimum risk High risk iii. Is there a benefit a) to the subject? Direct ☐ Indirect ☐ b) Benefit to society	Yes No	No No
11. Data Monitoring i. Is there a plan for reporting of adverse events? **If Yes,** reporting is done to: Sponsor, Ethics Committee ii. Is there a plan for interim analysis of data? iii. Are there plans for storage and maintenance of all trial database?	Yes Yes Yes Yes	No No No No
12. Is there compensation for injury? **If Yes** ☐ by Sponsor ☐ by Investigator ☐ by insurance ☐ by any other company	Yes	No

13. Do you have conflict of interest? (financial / nonfinancial) **If Yes, specify :**	Yes	No
14. Conflict of interest for any other investigator(s) (if yes, please explain in brief)	Yes	No
15. Participant Information Sheet attached	Yes	No
16. Participant Informed Consent Form attached	Yes	No
17. Whether any work on this project has started or not?	Yes	No

Annexure 8C

Checklist for study proposals.

Covering letter, through proper channel with Title of the study	
Project proposal Hard and Soft Copies	
Brief description of proposal	
Patient information sheet	
Informed Consent form	
Attach Questionnaire/ proforma	
Statement of conflict of Interest	
Others	

ANNEXURE-8D

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

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. In case of any adverse reaction, PI must be informed immediately.
8. 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
9. Telephone number/ contact number of Principle investigator and Co-Investigator at the top of each page
10. Self-certification should be given that the translation to vernacular language is correct.

UNDERTAKING FOR ETHICS COMMITTEE ATTACHED TO HOSPITAL

(1) I declare that I, DR. HARPREET SINGH S/o, D/o, W/o, S. INDER PAUL SINGH Age 42 am working as PRINCIPAL, PROFESSOR Managing Director/Director/Chief Executive Officer/Chief Operating Officer/Secretary/ Head of the Institute - in case of Government/ Semi - Government/Govt. Autonomous Body, (strike off whichever is not applicable) of M/s BJS DENTAL COLLEGE HOSPITAL & RESEARCH INSTITUTE having our Hospital/Institute at SECTOR-40, URBAN ESTATE, CHD. ROAD, LUDHIANA 141010 (complete address). My contact details are as follows –
Landline No. 0161-5055162 Mob. No. 9815493618 E-mail Id: bjsdental@rediffmail.com

(2) I undertake that I am representing M/s BJS DENTAL COLLEGE HOSPITAL & RESEARCH INSTITUTE (Firm/Hospital/Institute) and this undertaking is given for registration of the Ethics Committee.

(3) I am the competent authority/ authorized by the competent authority of the Firm/Hospital/Institute/Organization to delegate this power of attorney.

(4) I have read the terms, conditions and privacy policy of the Department of Health and Research (DHR) portal i.e., https://naitik.gov.in and agree to them.

(5) I authorize Shri/Smt DR. SUNAINA JODHKA S/o, D/o, ~~W/o~~ MR. KULBIR S. JODHKA, Age 43yrs holding the position of Member Secretary of the Ethics Committee for Biomedical and Health Research involving Human Participans namely, B.J.S. DENTAL COLLEGE INSTITUTIONAL ETHICS COMMITTEE (name of Ethics Committee) in our Firm/Hospital/Institute/Organization to register on the DHR portal https://naitik.gov.in.
The contact details are as follows:
Landline No. 0161-5055163 Mobile No. 98151-82368
Emal ID drsunaina79@yahoo.com.sg

(6) I undertake that the applicant will be held responsible for all the acts and deeds performed on the DHR portal https://naitik.gov.in subsequent to the registration of the Ethics Committee.

(7) I undertake that the login password will be kept confidential and that I will be held responsible for sharing the same with unauthorized persons.

(8) The information submitted above is true and correct to the best of my knowledge and no part of it is false and nothing has been concealed.

(9) I declare that no other person has been authorized by me, to register on the portal for this purpose.

(10) I declare that all the submissions and communications made are on the behalf of the Chairman of the Ethics Committee, who has given me the authority in writing to do so.

Signature:
Name (In capital letters): DR. HARPREET SINGH
Designation: 20.7.2022
Seal: Principal, Baba Jaswant Singh Dental College Hospital & Research Institute, Ludhiana.

Signed on 20.7.2022
Place: LUDHIANA