INSTITUTIONAL ETHICS COMMITTEE (IEC)

The first International statement on the ethics in medical research using human subjects, the Nuremberg Code was formulated in 1947 and it laid emphasis on consent and voluntariness. In 1964, the eighteenth World Medical Assembly at Helsinki, Finland adopted a code of ethics for the guidance of doctors involved in clinical research. This is popularly known as the "Declaration of Helsinki." In 1980, the Indian Council of Medical Research released a 'Policy Statement on Ethical Considerations involved in Research in Human Subjects' for the benefit of all those involved in clinical research in India.

Moreover in 1996, the International Conference on Harmonization (ICH) published a tripartite guideline for Good Clinical Practice (GCP) to harmonize technical requirements for registration of pharmaceutical products in three regions namely the United States, the European Union and Japan). Today, the ICH-GCP guideline is followed globally for clinical research. This guideline elaborates the composition and functioning of an Institutional Ethics Committee to review clinical research proposals.

It was thus felt necessary to establish an Institutional Ethics Committee (IEC) consistent with the GCP Guidelines so as to facilitate the ethical review of any human research projects at institute. Yogita dental college and Hospital, khed is an under-graduate and postgraduate medical teaching institution with all ultra-modern health care services with 1500 hundred indoor admission bed capacities. The institution provides support for conducting research on human subjects to researchers (self-funded) or those offered by the sponsored pharmaceutical companies. To protect interest of participating subjects it was felt necessary to start an institutional ethics committee for reviewing the scientific as well as ethical aspects in the projects planned in Yogita dental college and Hospital, khed

The Institutional Ethics Committee presently functions according to the requirements laid down in Ethical Guidelines for Biomedical Research on Human Subjects laid down by the Indian Council of Medical Research (ICMR) 2018, and is guided by the guidelines for Good Clinical Practice (GCP), ethical principles set forth in the Declaration of Helsinki.

Objectives:

- To ensure the protection of the rights, safety and well-being of human subjects involved in a research project.
- To provide public assurance of that protection.

Strategic plan of action:

- The Institutional Ethics Committee (IEC) is established under the authority of Dean, Yogita dental college and Hospital, khed. It is administratively governed under same authority.
- Institution will support establishment of ethics committee including training, resources and infrastructure etc.
- The IEC is an independent committee chaired by external personnel and has its own function and decision making. Institute management will not participate in its functioning and decision making. Dean, Yogita dental college and Hospital, khed will ensure independence of the IEC.

- The IEC shall adhere to existing applicable rules and regulations (Ethical Guidelines for Biomedical Research on Human Subjects laid down by the Indian Council of Medical Research (ICMR) 2018, CDSCO guidelines, ICH-GCP, Indian GCP, ICMR guidelines etc.) for its formation, registration, functioning etc.
- All research projects involving human participation must be approved by the IEC.
- Each project along with a duly completed application/submission form shall be submitted through electronic copy (PDF format) and at least 3 paper sets of the same. The application form will be available at the office of the IEC. The information to be given on the application form shall be filled in legible handwriting. It shall have the designation and signatures of Principal Investigator. All details in the form such as type of patients phase of drug trial, duration of study, sponsoring agency, budget of the trial, availability of Drugs Controller General of India [DCGI] permission and other relevant approvals etc. shall be completed while submitting the proposal.
- Studies which plan to use a new drug (as defined in 122-E of the Drugs and Cosmetics Act, 1945) shall submit along with the Protocol submission application form, a copy of the permission letter issued by the DCG(I) to the pharmaceutical company/investigator. If the DCGI permission is awaited, a letter of provisional approval from EC will be issued and final EC approval will be given after a copy of DCGI permission is submitted to the EC. A study cannot begin until the final letter of permission is issued by the EC.
- In case a clinical study is planned on an "alternative system of medicine" a co-investigator from that system will be required on that study. For Ayurveda or herbal drugs, which are not marketed, a copy of the marketing/manufacturing license issued by FDA to the company shall be submitted.
- All required fees shall be collected at the time of submission of the project. The amount to be collected, as processing fee will be reviewed at the end of 1 year.
- The project proposal shall be submitted in soft copy (PDF format) via email and three hard copies. Documents should be submitted to at least 21 days prior to scheduled ethics committee meeting for initial review and amended documents. Each set shall contain the documents on A4 size paper arranged in a file in the order mentioned below:

1. EC application form duly filled
2. Summary of protocol or Protocol Synopsis
3. Protocol and any amendments to it with version and date
4. The informed consent document (ICD), including any amendments / addendum and its translation(s) into regional language(s)
5. A copy of Informed Consent Document for Audio visual Consent, if applicable
6. Case Record Form (CRF) / Questionnaire.
7. Principal investigator's current Curriculum vitae.
8. Subject recruitment procedures (e.g. advertisements/letters to doctors/posters)
9. Investigator Brochure (This should give details of the study drug, toxicology studies, phase I, II, III data wherever available, safety information etc)
10. Insurance policy (if applicable)
11. DCG(I) clearance [for Phase I, II, III studies on new drugs and other studies as applicable as per Schedule 'Y' of the Drugs and Cosmetics Act]
12. Investigator's agreement with sponsor
13. Investigator's undertaking to DCG(I) [for Phase I, II, III studies]
14. Health Ministry Screening Committee (HMSC) clearance wherever applicable

15. Food and Drug Administration (FDA) marketing/manufacturing license for herbal drugs
16. Any other applicable documents

- All communications with the committee shall be in writing.
- The project proposals in the format mentioned in § 9.1 above will be accepted in office of the IEC as a soft copy (PDF format) and at least 3 set of paper copies.
- The submitted project/s will be circulated 14 days prior to the IEC meeting for initial review to all committee members via email or paper copy and the proposal shall be reviewed
- A meeting, of all members will be held preferably once every 2 months where each proposal will be discussed and decisions arrived at. Any extra meeting required on urgent basis, respective proposal will be considered as expedite submission and has to pay IEC fees
- All members of the IEC present during meeting will be responsible for review of projects. However, members are expected review specific documents in detail which are in their own expertise (e.g. legal expert are expected to review Clinical trial agreement and insurance policy).
- Every reviewing need to fill study assessment form present during meeting. Study assessment form can be share either as Signed Hard copy or filled soft copy through email. Admin officer will keep all filled Study assessment form in respective study project file.
- When there are no research proposals to review, the meeting may be held less frequently, but not less than once every 12 weeks.
- All members will receive notification of meeting schedules at least 1 week in advance.
- The committee members will review all the proposals before the meeting.
- The proposal may be sent to a subject expert for his/her assessment and opinion of the research proposal. The subject expert may be invited for the meeting.
- The investigator and/ or co-investigator may be invited to the meeting to provide clarifications on the study protocol. Member Secretary will invite concern investigator and/ or co- investigator for meeting if required
- The Member Secretary will be responsible for coordination and recording of the proceedings of the meeting.
- The proceedings of the meetings shall be recorded in English and in the form of minutes.
- The minutes shall be approved by the chairperson and circulated within 14 days of the EC meeting.
- Decision for each proposal shall be voting by simple majority.
- A majority vote for approval, disapproval, and request for modifications, suspension or termination of a research proposal or an ongoing study is defined as one-half of the members who have reviewed the project.
- All members present at the IEC will vote on the research proposal.
- Absent members will not vote.
- Member(s) of the committee who is/are listed as investigator(s) on a research proposal or having conflict of interest will opt out from all deliberations on the proposal and will not vote on the proposal.
- An investigator or study team member invited for the meeting will not vote or participate in the decision making procedures of the committee.

- Specific patient groups or Subject experts shall be invited for the meeting will not vote or participate in the decision making procedures of the committee.
- The outcome of committee's review shall be communicated to the investigator within 14 working days of the meeting and the reply for the same must be submitted by the principal investigator within 5 days of receipt of the letter. If there is no reply or any other communication within 5 days, the project will be considered closed and shall be archived When modifications to the proposal, as recommended by the committee, are minor, the revised documents may not be re- circulated. The revised proposal shall be reviewed by either the Chairperson of the committee, the Member Secretary of the committee, or by one or more experienced reviewers designated by the chairperson from among the members of the committee. An approval may then be issued if the revised documents are satisfactory. The committee will keep all members of the committee informed of these approvals.
- When modifications to the proposal, as recommended by the committee, are major, the revised proposal will be re-circulated and discussed again at next meeting.

Risk categories as per Ethical Guidelines for Biomedical Research on Human Subjects laid down by the Indian Council of Medical Research (ICMR) 2018 and type of review

TYPE OF RISK	DEFINITION/DESCRIPTION	TYPE OF REVIEW
Less than minimal risk	Probability of harm or discomfort anticipated in the research is nil or not expected. For example, research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.	IRRC or SAC approval considered final
Minimal Risk	Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Examples include research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.	Expedited review
Minor increase over minimal risk or Low risk	Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. This may present in situations such as routine research on children and adolescents; research on persons incapable of giving consent; delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials; use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; trying a new diagnostic technique in pregnant and breastfeeding women, etc. Such research should have a social value. Use of personal identifiable data in research also imposes indirect risks. Social risks, psychological harm and discomfort may also fall in this category.	Full board review

TYPE OF RISK	DEFINITION/DESCRIPTION	TYPE OF REVIEW
More than minimal risk or high risk	Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures, etc.	Full board review