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Institutional Human Ethics Committee

Standard Operating Procedures (SOP)

Version: 2.0 (Aligned with ICMR Guidelines, 2017)
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(Based on *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants of ICMR 2017)*

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Institutional Human Ethics Committee
Standard Operating Procedures

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OBJECTIVE

The objective of this SOP is to put in place an effective and consistent ethical review mechanism for health and biomedical research for all proposals submitted by the faculty and students of the college as prescribed by the Ethical guidelines for biomedical research on human participants of ICMR (*National Ethical Guidelines for Biomedical and Health Research Involving Human Participants of ICMR 2017*).

In the event of any dispute or confusion, the provisions and interpretations outlined in the 'National Ethical Guidelines for Biomedical and Health Research Involving Human Participants' (ICMR, 2017) and any subsequent amendments shall be considered final.

PURPOSE AND SCOPE OF THE PROPOSED EC

The **purpose** of the proposed Ethics Committee is to ensure that all research involving human participants at Km. Mayawati Government Girls P.G College, Badalpur, G.B. Nagar adheres to the highest ethical and scientific standards, thereby protecting the participants from any harm and ensuring ethical integrity in the conduct of research.

The **scope** of the proposed EC includes:

- All **biomedical, social, and behavioral health research** involving human participants, their biological material, and data.
- Research conducted by students (such as MSc, MA, PhD theses), faculty, staff, and investigators associated with the institution.
- **Externally sponsored, collaborative, and investigator-initiated studies**.
- **Multi-centric studies** and clinical trials with due registration under CDSCO or CTRI, wherever applicable.
- **Academic research proposals** including postgraduate dissertations and fellowships. Studies conducted under **national health programs** or **public health initiatives**.
- In the event of any confusion or conflict, the provisions outlined in the ICMR's *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants* (2017) shall be considered final and binding..

GENERAL ETHICAL ISSUES

All research involving human participants should be conducted in accordance with the basic and general ethical principles as outlined in section 1 of ICMR guidelines 2017. The researcher and the team are responsible for protecting the dignity, rights, safety and well-being of the participants enrolled in the study. They should have the appropriate qualifications and competence in research methodology and should be aware of and comply with the scientific, medical, ethical, legal and social requirements of the research proposal. The ECs are responsible for ensuring that the research is conducted in accordance with the aforementioned principles.

BENEFIT-RISK ASSESSMENT:

- Benefits to the individual, community or society refer to any sort of favourable outcome of the research, whether direct or indirect. The social and scientific value of research should justify the risk, which is the probability of causing discomfort or harm anticipated as physical, psychological, social, economic or legal.
- The researcher, sponsor and EC should attempt to maximize benefits and minimize risks to participants so that risks are balanced to lead to potential benefits at individual, societal and/or community levels.
- The EC should assess the inherent benefits and risks, ensure a favourable balance of benefits and risks, evaluate plans for minimizing the risk and discomfort and decide on the merit of the research before approving it.
- The EC should also assess any altered risks in the study at the time of continuing review.
- The type of EC review based on risk involved in the research, is categorized as given in following Table.

INFORMED CONSENT PROCESS

Informed consent protects the individual's autonomy to freely choose whether or not to participate in the research. The process involves three components – providing relevant information to potential participants, ensuring the information is comprehended by them and assuring voluntariness of participation. Informed consent should explain medical terminology in simple terms and be in a language that the participant understands.

Table : Categories of Risk	
Type of risk	**Definition/description**
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.
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.
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.
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.

- The informed consent document (ICD), which includes patient/participant information sheet (PIS) and informed consent form (ICF) should have the required elements and should be reviewed and approved by the EC before enrolment of participants. For all biomedical and health research involving human participants, it is the primary responsibility of the researcher to obtain the written, informed consent of the prospective participant or legally acceptable/authorized representative (LAR). In case of an individual who is not capable of giving informed consent, the consent of the LAR should be obtained. If a participant or LAR is illiterate, a literate impartial witness should also be present during the informed consent process.
- In certain circumstances audio/audio-visual recording of the informed consent process may be required, for example in certain clinical trials as notified by CDSCO.
- Verbal/oral consent/waiver of consent/re-consent may be obtained under certain conditions after due consideration and approval by the EC. See section 5 of ICMR,2017 for further details.

PRIVACY AND CONFIDENTIALITY

- Privacy is the right of an individual to control or influence the information that can be collected and stored and by whom and to whom that information may be disclosed or shared. Confidentiality is the obligation of the researcher/research team/organization to the participant to safeguard the entrusted information. It includes the obligation to protect information from unauthorized access, use, disclosure, modification, loss or theft.
- The researcher should safeguard the confidentiality of research related data of participants and the community.
- Potential limitations to ensure strict confidentiality must be explained to the participant. Researchers must inform prospective participants that although every effort will be made to protect privacy and ensure confidentiality, it may not be possible to do so under certain circumstances.
- Any publication arising out of research should uphold the privacy of the individuals by ensuring that photographs or other information that may reveal the individual's identity are not published. A specific re-consent would be required for publication, if this was not previously obtained.
- Some information may be sensitive and should be protected to avoid stigmatization and/or discrimination (for example, HIV status; sexual orientation such as lesbian, gay, bisexual, and transgender (LGBT); genetic information; or any other sensitive information).
- While conducting research with stored biological samples or medical records/data, coding or anonymization of personal information is important and access to both samples and records should be limited. See section 11 for further details.
- Data of individual participants/community may be disclosed in certain circumstances with the permission of the EC such as specific orders of a court of law, threat to a person's or community's life, public health risk that would supersede personal rights to privacy, serious adverse events (SAEs) that are required to be communicated to an appropriate regulatory authority etc.

DISTRIBUTIVE JUSTICE

- Efforts must be made to ensure that individuals or communities invited for research are selected in such a way that the benefits and burdens of research are equitably distributed.
- Vulnerable individuals/groups should not be included in research to solely benefit others who are better-off than themselves.
- Research should not lead to social, racial or ethnic inequalities.
- Plans for direct or indirect benefit sharing in all types of research with participants, donors of biological materials or data should be included in the study, especially if there is a potential for commercialization. This should be decided a priori in consultation with the stakeholders and reviewed by the EC.

PAYMENT FOR PARTICIPATION

- If applicable, participants may be reimbursed for expenses incurred relating to their participation in research, such as travel-related expenses. Participants may also be paid for inconvenience incurred, time spent and other incidental expenses in either cash or kind or both as deemed necessary (for example, loss of wages and food supplies).
- Participants should not be made to pay for any expenses incurred beyond routine clinical care and which are research related including investigations, patient work up, any interventions or associated treatment. This is applicable to all participants, including those in comparator/control groups.
- If there are provisions, participants may also receive additional medical services at no cost.
- When the LAR is giving consent on behalf of a participant, payment should not become an undue inducement and to be reviewed carefully by the EC. Reimbursement may be offered for travel and other incidental expenses incurred due to participation of the child/ward in the research.
- ECs must review and approve the payments (in cash or kind or both) and free services and the processes involved and also determine that this does not amount to undue inducement.

COMPENSATION FOR RESEARCH-RELATED HARM

- Research participants who suffer direct physical, psychological, social, legal or economic harm as a result of their participation are entitled, after due assessment, to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability. In case of death, participant's dependents are entitled to financial compensation. The research proposal should have an in-built provision for mitigating research related harm.
- The researcher is responsible for reporting all SAEs to the EC within 24 hours of knowledge. Reporting of SAE may be done through email or fax communication (including on non-working days). A report on how the SAE was related to the research must also be submitted within 14 days.
- The EC is responsible for reviewing the relatedness of the SAE to the research, as reported by the researcher, and determining the quantum and type of assistance to be provided to the participants.

- For clinical trials under the purview of CDSCO, the timeline and procedures as notified from time to time may be followed.
- All research participants who suffer harm, whether related or not, should be offered appropriate medical care, psycho-social support, referrals, clinical facilities, etc.
- Medical management should be free if the harm is related to the research.
- Compensation should be given to any participant when the injury is related to the research. This is applicable to participants in any of the arms of research, such as intervention, control and standard of care.
- While deliberating on the quantum of compensation to be awarded to participants who have suffered research-related injury, the EC should consider aspects including the type of research (interventional, observational, etc.), extent of injury (temporary/permanent, short/long term), loss of wages, etc.
- For other sponsored research, it is the responsibility of the sponsor (whether a pharmaceutical company, government or non-governmental organization (NGO), national or international/bilateral/multilateral donor agency/institution) to include insurance coverage or provision for possible compensation for research related injury or harm within the budget.

- All AEs should be recorded and reported to the EC according to a pre-planned timetable, depending on the level of risk and as recommended by the EC.
- In investigator initiated research/student research, the investigator/institution where the research is conducted becomes the sponsor.
  - It is the responsibility of the]host institution to provide compensation and/or cover for insurance for research related injury or harm to be paid as decided by the EC.
  - The institution should create in-built mechanism to be able to provide for compensation, such as a corpus fund in the institution.
  - In the applications for research grants to funding agencies – national or international, government or non-government agencies – the researcher should keep a budgetary provision for insurance coverage and/or compensation depending upon the type of research, anticipated risks and proposed number of participants.

ANCILLARY CARE

- Participants may be offered free medical care for non-research-related conditions or incidental findings if these occur during the course of participation in the research, provided such compensation does not amount to undue inducement as determined by the EC.

CONFLICT OF INTEREST

- Conflict of interest (COI) is a set of conditions where professional judgement concerning a primary interest such as participants welfare or the validity of research tends to be unduly influenced by a secondary interest, financial or non-financial (personal, academic or political). COI can be at the level of researchers, EC members, institutions or sponsors. If COI is inherent in the research, it is important to declare this at the outset and establish appropriate mechanisms to manage it.
- Research institutions must develop and implement policies and procedures to identify, mitigate conflicts of interest and educate their staff about such conflicts.
- Researchers must ensure that the documents submitted to the EC include a disclosure of interests that may affect the research.
- ECs must evaluate each study in light of any disclosed interests and ensure that appropriate means of mitigation are taken.
- COI within the EC should be declared and managed in accordance with standard operating procedures (SOPs) of that EC.

ROLE AND RESPONSIBILITIES

IHEC will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and well being of the research subjects/participants. The IHEC will take care that all the cardinal principles of research ethics viz Autonomy, Beneficence, Non - maleficence and Justice are taken care of in planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures, such as annual reports, final reports and site visits etc. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws. The mandate of the IHEC will be to review all research projects involving human subjects including human biological materials and human biological data to be conducted at the college, irrespective of the funding agency.

Responsibilities include:

- Initial and continuing review of research proposals.
- Monitoring of ongoing studies for compliance.
- Reviewing serious adverse events and protocol deviations.
- Ensuring appropriate record-keeping, archival, and reporting practices.
- Facilitating capacity building of EC members and researchers.

COMPOSITION

IHECs should be multidisciplinary and multisectorial approach in composition. Independence and competence are the two hallmarks of an IHEC. The number of persons in an ethical committee will be around 10-20 members. The Chairperson of the Committee should be from outside the College and not head of the College to maintain the independence of the Committee. The Member Secretary will be a faculty member from the college to conduct the business of the Committee. Other members will be a mix of medical / non-medical, scientific and non-scientific persons including lay public to reflect different viewpoints

- ECs should be multi-disciplinary and multi-sectoral.
- There should be adequate representation of age and gender.
- Preferably 50% of the members should be non-affiliated or from outside the institution.
- The number of members in an EC should preferably be between 10 and 20 and a minimum of five members should be present to meet the quorum requirements.
- The EC should have a balance between medical and non-medical members/technical and non-technical members, depending upon the needs of the institution.
- The members will be appointed by the Principal of the College based on their competencies and integrity, and could be drawn from any public or private College/ Institute from anywhere in the country
- The composition, affiliations, qualifications, member specific roles and responsibilities are given in following Table.

Table : Composition, affiliations, qualifications, member specific roles and responsibilities of an EC

S. No.	Members of EC	Definition/description
1.	**Chairperson/** **Vice Chairperson** (optional) Non-affiliated Qualifications - A well-respected person from any background with prior experience of having served/ serving in an EC	• 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.
2.	**Member Secretary/ Alternate Member Secretary** (optional) Affiliated Qualifications - • Should be a staff member of the institution • Should have knowledge and experience in clinical research and ethics, be motivated and have good communication Skills • Should be able to devote adequate time to this activity which should be protected by the institution	• 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 secretariat and 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
3.	**Basic Medical Scientist(s)** Affiliated/ non-affiliated Qualifications - • Non-medical or medical person with qualifications in basic medical sciences • In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist	• 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 For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.
4.	**Clinician(s)** Affiliated/ non-affiliated Qualifications - • Should be individual/s with recognized medical qualification, expertise and training	• 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.
5.	**Legal expert/s** Affiliated/ non-affiliated Qualifications - • Should have a basic degree in Law from a recognized university, with experience • Desirable: Training in medical law.	• Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc. • Interpret and inform EC members about new regulations if any
6.	**Social scientist/ philosopher/ ethicist/theologian** Affiliated/ non-affiliated Qualifications - • Should be an individual with social/ behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities	• 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.
7.	**Lay person(s)** Non-affiliated Qualifications - • Literate person from the public or community • Has not pursued a medical science/ health-related career in the last 5 years • May be a representative of the community from which the participants are to be drawn • Is aware of the local language, cultural and moral values of the community • Desirable: involved in social and community welfare activities	• 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.

There should be adequate representation of age, gender, community, etc. in the Committee to safeguard the interests and welfare of all sections of the community / society. Members should be aware of local, social and cultural norms, as this is the most important social control mechanism. If required, subject experts could be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist, should be included. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Committee.

TENURE AND CHANGES OF EC MEMBERS

- The tenure for the EC and its members is 3 years.
- At the end of 3 years, the committee is to be reconstituted, and 20% of the members will be replaced by a defined procedure.
- A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
- A member can tender resignation from the committee with proper reasons to do so.
- All members should maintain absolute confidentiality of all discussions during the meeting.
- Conflict of interest should be declared by members of the IHEC
- Members of the EC should not have any known record of misconduct.

QUORUM REQUIREMENTS

The minimum of 5 members are required to compose a quorum. All decisions should be taken in meetings and not by circulation of project proposals. This quorum must include at least one non-scientific member that may either be a lawyer, philosopher, member of NGO or a lay person from the community.

- A minimum of five members presents in the meeting (online/ offline/Blended).
- The quorum should include both medical, non-medical or technical or/and non-technical members.
- Minimum one non-affiliated member should be part of the quorum.
- Preferably the lay person should be part of the quorum.
- The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.
- No decision is valid without fulfilment of the quorum

AUTHORITY UNDER WHICH IHEC IS CONSTITUTED

- The Principal of Km. Mayawati Govt. Girls P.G. College, Badalpur, G.B. Nagar have the power to constitute the IHEC.

OFFICE

IHEC, Dept. of Zoology, Km. Mayawati Government Girls P.G. College, Badalpur, G.B. Nagar-203207 is the office of IHEC.

MEETINGS

The Chairperson will conduct all meetings (offline/Online/Blended) of the IHEC. If for reasons beyond control, the Chairperson is not available, the Deputy Chairperson 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 before communicating to the researchers with the approval of the appropriate authority.

INDEPENDENT CONSULTANTS

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

APPLICATION PROCEDURES

- All proposals should be submitted in the prescribed application form.
- All relevant documents should be enclosed with application form.
- Processing fee should be submitted to IHEC office.
- A soft copy of the proposal along with the application in prescribed format duly signed by the Guide /Principal Investigator (PI) and Co-investigators / Collaborators must be sent to the member secretary.
- The date of meeting will be intimated to the researcher to be present for clarification.
- The decision will be communicated in writing. If revision is to be made, the revised document should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

DOCUMENTATION (APPLICATION FORM)

For a thorough and complete review, all research proposals should be submitted with the following documents:

1. Title of the project.
2. Name of the applicant with designation.
3. Name of the College/ Hospital / Field area where research will be conducted.
4. Forwarded by the Head of the Institution /Head of the Department.
5. Protocol of the proposed research
6. List of Ethical issues in the study and plans to address these issues.
7. Proposal should be submitted with all relevant enclosures like proformae, case report forms, questionnaires, follow - up cards, etc.
8. Informed consent process, including patient information sheet and informed consent form in local language(s).
9. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country / countries, if available.
10. Curriculum vitae of all the investigators with relevant publications in last five years.
11. Any regulatory clearances required.
12. Source of funding and financial requirements for the project.
13. Other financial issues including those related to insurance
14. An agreement to report all Serious Adverse events(SAEs)
15. Statement of Conflict of interests, if any
16. An agreement to comply with all national and international guidelines
17. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable;
18. All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.
19. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.
20. Any other information relevant to the study

REVIEW:

- The meeting of the IHEC should be held at least once in a year or as per the requirement.
- The proposals will be sent to members at least 8- 10 days in advance.
- Decisions will be taken by consensus after discussions, and whenever needed voting will be done.
- Researchers will be invited to offer clarifications if need be.
- Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed.
- The decisions will be minuted and Chairperson's approval taken in writing.

ELEMENTS OF REVIEW

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

TYPES OF PROJECTS UNDER PURVIEW

Under the **Biomedical and Health Research** domain, the EC will review:

- **Academic research** (e.g., MSc, MA, PhD thesis/reports/ dissertations).
- **Investigator-initiated studies**.
- **Pharmaceutical-sponsored trials**, including bioavailability/bioequivalence studies.
- **Public health research** and **community-based studies**.
- **Behavioral and socio-cultural studies** affecting health.
- Research involving **use of stored biological samples**, **biobanking**, or **genetic data**.

REVIEW OF PROPOSALS FROM OUTSIDE THE INSTITUTION

The EC may accept research proposals from external institutions (user institutions) under the following **conditions**:

- Prior **MoU** or **formal agreement** must be established between the host (reviewing) and user institutions.
- The external institution must lack its own EC and be located preferably in the **nearby geographic area** (ICMR Guidelines, Section 4.2).
- Proposals must follow the same **submission, scrutiny, and monitoring procedures** as internal proposals.
- There will be **no compromise** in scientific and ethical review standards.

REVIEW FEE STRUCTURE

- **Academic proposals-Public sector HEIs** (e.g., MSc, MA, PhD.): ₹500
- **Academic proposals-Private sector HEIs** (e.g., MSc, MA, PhD.): ₹2,000
- **Investigator-initiated funded projects**: **Public sector (**₹500), **Private sector (**₹5000)
- **Industry-sponsored clinical trials**: ₹25,000
- **Fee exemption-**No fee charges form the member of EC and Non-professional UG students' proposals.
- **Protocol amendments** and continuing review: ₹5,000–₹10,000 (based on workload)

Note: The final fee may vary depending on the complexity of the study and institutional policy. Waivers can be considered on a case-to-case basis for student or government projects.

BANK ACCOUNT

A separate joint bank account is opened in bank in the name of Principa and Members Secretary or as decided in the meeting EC.

EXPEDITED REVIEW

All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of identified members convened by the Chairperson to expedite decision making. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review. The nature of the applications, amendments, and other considerations that will be eligible for expedited review should be specified. To expedite review a sub-committee consisting of the member secretary, a non-scientific and a scientific member maybe constituted under the Deputy Chairperson to review the proposal and approved by the Chairperson.

DECISION MAKING

- Members will discuss the various issues before arriving at a consensus decision.
- 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.
- Decisions will be made only in meetings where quorum is complete.
- Only members can make the decision. The expert consultants will only offer their opinions.
- Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
- In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
- Modified proposals may be reviewed by an expedited review through identified members.
- Procedures for appeal by the researchers should be clearly defined.

COMMUNICATING DECISION

- Decision will be communicated by the Member Secretary in writing.
- Suggestions for modifications, if any, should be sent by IHEC.
- Reasons for rejection should be informed to the researchers.
- The schedule / plan of ongoing review by the IHEC should be communicated to the PI.

FOLLOW UP

- Reports should be submitted at annually for review.
- Final report should be submitted at the end of study.
- All SAEs and the interventions undertaken should be intimated.
- Protocol deviation, if any, should be informed with adequate justifications.
- Any amendment to the protocol should be resubmitted for renewed approval.
- Any new information related to the study should be communicated.
- Premature termination of study should be notified with reasons along with summary of the data obtained so far.
- Change of investigators / sites should be informed.

RECORD KEEPING AND ARCHIVING

- Curriculum Vitae (CV) of all members of IHEC.
- Copy of all study protocols with enclosed documents, progress reports, and SAEs.
- Minutes of all meetings duly signed by the Chairperson.
- Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.
- Copy of all correspondence with members, researchers and other regulatory bodies.
- Final report of the approved projects/thesis.
- All documents should be archived for three years after the completion of project/thesis.
- Maintain adequate and accurate records after the completion or termination of biomedical & health research study for not less than 3 years from the date of completion or termination of the study (both in hard and soft copies)

UPDATING IHEC MEMBERS

- All relevant new guidelines should be brought to the attention of the members.
- Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area. Certificate of participation should be kept in record.

PROCEDURES AS PER SOP

Establishing and Constituting the

Institutional Human Ethics Committee (IHEC)

- The principal will select and nominate the Chairperson and Member Secretary for IHEC-AC.
- The IHEC will be constituted by the principal in consultation with the Chairperson.
- The principal will invite the members to join ethics committee by sending the official request letter.
- Members will confirm their acceptance to the principal by providing all the required information for membership.
- The principal will ensure that the IHEC is established in accordance with the applicable laws and regulations of the state, country and in accordance with the value and principles of communities they serve.
- Principal will designate and instruct the member secretary of IHEC to conduct the regular proceedings of IHEC for the institute.
- At regular intervals, Principal will review the functioning of IHEC.

Procedure for appointing Members for the IHEC

- The principal in consultation with Chairperson and member secretary will nominate the members of IHEC, who have the qualification and experience to review and evaluate the scientific, medical and ethical aspects of the proposed study.
- When needed, IHEC will invite subject experts to offer their views.
- The appointment of an IHEC member will be for 3 years.
- The principal may renew the appointment on the basis of the member's contribution.
- During the term, Principal in consultation with the Chairperson and member secretary can disqualify any member if, the contribution is not adequate and/or there is long period of (member) non availability.
- Members will have the right to discontinue from membership of IHEC after giving written notice at least one month in advance.
- Each member is required to sign the declaration and confidentiality agreement regarding IHEC activities.
- Principal can nominate IHEC members to undergo orientation programme in national and international developments in ethics.

Procedure for convening and conducting IHEC meetings

- The Member Secretary in consultation with the Chairperson may convene the IHEC meeting.
- Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the workload.
- All the IHEC meetings will be held regularly on scheduled dates that are announced and notified in advance.
- All the proposals will be received at least two weeks before the meeting and should be checked for completeness as per the requirement by the member secretary.
- Members will be given not less than 8 - 10 days' time in advance to review study proposals and the relevant documents.
- Minutes of the IHEC meetings, all the proceedings and deliberation will be documented.
- Signatures of the Chairperson and the Member Secretary will be obtained on the minutes of the meeting document. The minutes will be circulated to all the guides /HODs in case of student proposals.
- Applicant, sponsors or investigators may be invited to present the proposal or elaborate on specific issues.
- Independent experts may be invited to the meeting or to provide written comment, subject to the applicable confidentiality agreement. They will not have a role in decision making.

Procedure for submission of research proposals for review by Ethics (Regular and Sub) Committee

- All investigators are responsible for implementing this SOP. Every protocol or amendment submitted for review to IHEC must contain number, version and date.
- All the research proposals must be submitted in the prescribed application form, duly filled, along with all necessary documents for the review.
- Processing fee should be submitted to IHEC office.
- Proposals may be submitted for review only after the approval of RDC of University/ different scientific funding agencies. Proof of approval needs to be submitted.
- Application can be submitted to the office of the Member Secretary, IHEC, K.M. Govt. Girls P.G. College, Badalpur on any working day.
- All the proposals and documents must be submitted at least two weeks in advance from the scheduled date of IHEC meeting
- Five copies of study proposal (with all documents) must be submitted for Regular Ethic Committee review and a soft copy of the proposal must also be submitted in a CD.
- Receipt of the application will be acknowledged by the IHEC office.
- Every application will be allotted an IHEC registration number to be used for all future correspondence and reference.

Procedure for reviewing the research proposals

- Every proposal will be sent not less than 10 days before the meeting to all members of IHEC. They will evaluate them on ethical issues, scientific soundness and technical excellence of the proposed research, before it is taken up for main IHEC review.
- All the members will evaluate the possible risks to the study participants with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue.
- The IHEC review will be done through formal meetings and will not resort to decision through circulation of proposal.
- Expert opinion of additional members would be obtained if necessary.

Procedure for expedited review of research proposals by Ethics Sub-Committee

- IHEC will receive and consider the proposals for expedited review and approval for the studies having/involving:
  i. No or minimum risk to the trial participants.
  ii. Re examination of a proposal already examined by the IHEC.
  iii. Study of minor nature like the examination of case records.
  iv. Similar study proposal for which IHEC had already given approvals earlier.
  v. An urgent proposal of national interest having minimum risk.
- All other proposals which do not comply with the above criteria will be reviewed in the Regular Ethics Committee meeting.
- All expedited approvals will be given in a meeting of the Sub-Committee of three members (nominated by the Chairperson). All the three members including the Member Secretary should be present for the meeting.
- Decision taken by the Sub-Committee on expedited approval will be brought to the notice of the main committee members at the next regular meeting of the IHEC.

Procedure for decision making regarding the research project/ Thesis/Dissertation

- Member having a conflict of interest will indicate to the Chairperson prior to the review of application and same will be recorded in the minutes.
- Where there is a conflict of interest, member will withdraw from the decision making procedure.
- A decision will only be taken when sufficient time has been allowed for the review and discussion of an application in the absence of non members (e.g. Investigator) from the meeting.
- Decision will only be taken at meetings where a quorum (5 members from total nine members) is complete.
- Decision will be taken only after reviewing a complete application with all the required documents necessary for proposal.

- Only IHEC members who participated in review and discussion will participate in decision making.
- Wherever possible, the decision will be arrived through consensus and not by vote, but when a consensus appears unlikely voting can be resorted to.
- Decision will specify the conditional decision if any, with clear suggestions and re-review procedure.
- Rejection of proposal will be supported by clearly stated reasons.
- A decision of the IHEC will be communicated to the applicant in writing, within 10 days of the meeting at which the decision was taken in the specified format with signature of the member secretary with date.
- A certificate of approval will be sent to the applicant within 2 weeks.
- All the approvals will be valid for only three years or for the duration of the project whichever is less. Investigator has to get his or her project re-approved after three years if necessary.

Procedure for follow-up of research proposals by Ethics Committee

- IHEC 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.
- Progress of all the research proposals will be followed at a regular interval of at least once a year. But in special situations, IHEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.
- Following instances and events will require the follow-up review:
    i. Any protocol amendment likely to affect rights, safety or well being of research subject of conduct of study.
    ii. Serious or unexpected ADR 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 the applicant indicating modification/suspension/termination /continuation of the project.
- In case of premature suspension /termination, the applicant must notify the IHEC of the reasons for suspension/termination with a summary of results.
- Applicant must inform the time of completion of study and must send the result summary to IHEC. IHEC must receive a copy of final summary of study completed from the applicant.

Procedure for documentation and archiving of documents and communications of IEC

- All the documents and communications of IHEC will be dated, filed and archived in a secure place.

- Only persons, who are authorized by the Chairperson of IHEC, will have the access to the various documents.
- All the documents related to research proposals will be archived for a minimum period of 3 years from the completion /termination of the study.
- No document (except agenda) will be retained by any IHEC member.
- At the end of each meeting, every member must return all the research proposals and documents to IHEC office staff. They will archive one copy in IHEC office and other copies will be destroyed after one year.
- Following documents will be filed and archived with proper label on the top of file for easy identification of proposal.
    i. The constitution, written standard operating procedures of the IHEC, and regular (annual) reports.
    ii. The curriculum vitae of all IHEC members.
    iii. A record of all income and expenses if any, of the IHEC, including allowances and reimbursements made to the secretariat and IHEC members.
    iv. The published guidelines for submission established by the IHEC.
    v. The agenda of the IHEC meetings.
    vi. The minutes of the IHEC meetings.
    vii. One copy of all material submitted by an applicant.
    viii. A copy of the decision and any other correspondence sent to an applicant.
    ix. All written documentation received during the follow-up.
    x. The notification of completion, premature suspension, or premature termination of study.
    xi. The final summary or final report of the study.

Institutional Human Ethics Committee
Km. Mayawati Govt. Girls P.G. College, Badalpur

Review letter No. IHEC-AC/ Date: _____

To,

_____

_____

The _____ meeting of the Institutional Human Ethics Committee for the year _____ was held in K.M. Govt. Girls P.G. College, Badalpur, on_____ under the chairmanship of _____. Besides the Chairperson and Deputy Chairperson, _____ (Member Secretary), _____ (Member), _____ (Member), attended the meeting.

After the proceedings, the proposals listed for the meeting were taken up for discussion.
After deliberations, the following decisions were arrived:

- No. of proposals reviewed - _____
- No. of proposals approved - _____
- No. of proposals approved subject to corrections - _____

The recommendations made by the committee are given below.

The investigators whose proposals need minor modifications are required to send three copies of revised proposals to _____, Member-Secretary. If the revision is satisfactory, the approval certificate will be issued after consulting the Chairperson of committee.

The recommendations of the committee to each proposal are detailed below:

DEPARTMENT _____

Sl No.
Reg. No.
Name of the student/Principal Investigator
Title of Thesis/dissertation/Project
Name of Guide/co-Guide
Recommendations of the committee

Any change, modification or deviation in the protocol, or any serious adverse event must be informed to ethics committee within fourteen days. Any protocol modification or amendment must receive IHEC approval. Investigator should conduct the study as per the recommended guidelines.

It is also confirmed that our ethics committee is constituted and functions as per Ethical Guidelines for Biomedical research on Human Subjects, issued by Indian Council of Medical Research (2017).

Member Secretary	Chairperson
Institutional Human Ethics Committee	Institutional Human Ethics Committee
Name:	Name:
Date:	Date:

FORM VERIFICATION OF PROPOSALS SUBMITTED TO INSTITUTIONAL HUMAN ETHICS COMMITTEE

*For official use only Proposal No.*_____

Yes, No or NA Comments

Comment	*Yes/ No/ NA*
Is all the documentation provided?	
Scientific importance and validity	
1. Will the study lead to improvements in human health and wellbeing or increase knowledge?	
2. Is there provision for dissemination of results of the research?	
3. Has the research protocol been approved by a competent body?	
4. Are the objectives stated clearly?	
5. Is the study design is appropriate?	
6. Are the investigators qualifications, competence and experience appropriate to conduct the study?	
7. Is the manner in which the results of research will be reported and published ethical?	
Assessment of Risks/Benefits	
8. Is the involvement of human participants necessary to obtain the necessary information?	
9. Are the researcher qualifications, competence, and experience suitable to ensure safe conduct of the study?	
10. Is the justification of predictable risks and inconveniences weighted against the anticipated benefits for the research participant and the concerned communities adequately?	
11. Are there any plans to withdraw or withhold standard therapy for the purpose of research and such actions if any justified?	
12. Is there provision for compensation for participants who sustain injuries?	
13. Have adequate provisions been made for dealing with and reporting adverse effects?	
14. Have adequate provisions been made for safety monitoring and termination of the research project?	
Respect for the dignity of the research participants Informed consent	
15. Is the process for obtaining informed consent appropriate?	
16. Are the participants competent to give consent?	
17. Is the justification adequate for the intention to include individuals who cannot consent?	
18. Is the written and oral information to be given to the research participants appropriate, adequate, complete and understandable?	
19. Do you approve the incentives offered?	

20. Is the consent given voluntarily and not due to deception, intimidation or inducement?	
Confidentiality	
21. Will the researcher collect only the minimum information/samples required to fulfill the study objectives?	
22. Is the privacy of the research participant safeguarded?	
23. Are data/sample storage and disposal procedures adequate?	
Rights of the participants	
24. Is the participant's right to unconditionally withdraw from the research at anytime safeguarded?	
25. Is there provision for participants to be informed about newly discovered risks or benefits during the study?	
26. Is there provision for the subjects to be informed of results of clinical research?	
Fair participant selection	
27. Has the study population been determined, primarily, based on the scientific goals of the study (and not on convenience, ethnicity, age, gender, literacy, culture or economic status)?	
28. Is the selection of participants (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized and the burden of research equitably distributed?	
29. Does the selection of participants stigmatize any group?	
30. Does selection of subjects favour any group?	
31. Is the research conducted on vulnerable individuals or groups?	
32. Is the research externally sponsored?	
33. Is the research a community research?	
34. Is the research a clinical trial?	
Responsibilities of the researcher	
35. Is the medical care to be provided to the research participants during and after the research adequate?	
36. Has the researcher obtained permission from the relevant authorities?	
37. Are there any conflicts of interest, including payments and other rewards?	
38. Are there any other ethical / legal/ social /financial issues in the study?	

Additional Comments, if any:

.....

.....

Recommendation: Approve [ ] Reject [ ] Conditional Approval (please state the conditions)

.....

.....

Signature :

Name of Reviewer:

Date :

Institutional Human Ethics Committee

Km. Mayawati Govt. Girls P.G. College, Badalpur,

(Affiliated to C.C.S. University, Meerut)

Registration Number……

No. IHEC. ……. Date: …….

CERTIFICATE

This is to certify that the project No. ……., entitled ……..“submitted by ……., has been approved by the Institutional Human Ethics Committee/Sub-Committee, at its meeting held on ……., under the following terms and conditions.

This approval is valid for three years or the duration of the project whichever is less.

Member Secretary

Institutional Human Ethics Committee

Km. Mayawati Govt. Girls P.G. College, Badalpur

G.B. Nagar-203207

APPLICATION FORM FOR PH.D-THESIS / MSC-DISSERTATION/ PROJECTS

Proforma along with consent forms to be submitted in 5 Copies along with a soft copy (Uploaded on Google link of EC) format to the *Member Secretary, Institutional Human Ethics Committee, Km. Mayawati Govt. Girls P.G. College, Badalpur.*

1	**Title of the project:**	
2	Name and department/address of the investigator:	
3	Name of Faculty (PI/CO-PI/Guide/Co-guide) with designation & department:	
4	Date of approval by funding agency/ RDC of University:	
5	Sources of funding:	
6	Objectives of the study:	
7	Justification for the conduct of the study:	
8	Methodology: It should provide details of number of volunteers /patients, inclusion criteria, exclusion criteria, control(s), study design, dosages of drug, duration of treatment, investigations to be done etc:	
9	Permission from Drug Controller General of India (DCGI) if applicable:	
10	Ethical issues involved in the study: *less than minimal risk/ minimal risk/ more than minimal risk to the study subjects (for guidance please consult ICMR guidelines 2006)*	
11	Do you need exemption from obtaining Informed Consent from study subjects – if so give justifications?	
12	Whether Consent forms part I and II in English and in Hindi language are enclosed?	
13	Conflict of interest for investigator(s) (if yes, please explain in brief)	

14. We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirements of the ICMR guidelines (2017)

Date: Signature of the Investigators

Date: Signature of the Head of the Department

(Note: The proforma must be accompanied by Consent forms I & II in English and Hindi. Consent form I is equivalent to Patient Information Sheet. The investigator must provide information to the subjects in a simple language, and it should address the subjects, in a dialogue format)

CONSENT FORM

PART I

INFORMATION FOR PARTICIPANTS OF THE STUDY

Instructions - This is the patient information sheet. It should address the participant of this study. Depending upon the nature of the individual project, the details provided to the participant may vary. A separate consent form for the patient/test group and control (drug/procedure or placebo) should be provided as applicable. While formulating this sheet, the investigator must provide the following information as applicable in a simple language in English and Hindi which can be understood by the participant

- Title of the project
- Name of the investigator/guide
- Purpose of this project/study
- Procedure/methods of the study
- Expected duration of the subject participation
- The benefits to be expected from the research to the participant or to others and the post trial responsibilities of the investigator
- Any risks expected from the study to the participant
- Maintenance of confidentiality of records
- Provision of free treatment for research related injury
- Compensation of the participants not only for disability or death resulting from such injury but also for unforeseeable risks.
- Freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant would otherwise be entitled
- Possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, this should be mentioned
- Address and telephone number of the investigator and co-investigator/guide
- The patient information sheet must be duly signed by the investigator

CONSENT FORM

PART II

CONSENT FORM (for the subject)

The advantages and disadvantages of the research in which I am expected to participate and/or for which I have to donate blood/tissue has been explained to me.

I willingly, under no pressure from the researcher (Please ✓)

☐ agree to take part in this research, and agree to participate in all investigations which will help acquire knowledge for the benefit of the mankind,
☐ agree to donate my blood/ tissue
☐ I am agree to use my survey data for research purposes

My consent is explicitly not for disclosing any personal information. For disclosing any such personal information obtained from the investigations conducted on my samples, further consent should be obtained.

I have been informed that the guide/ researchers/ PI and her/his research student will take my prior consent before they draw benefits from research based on my samples.

Signatures:

| --- | --- | --- |
| Subject | Witness | Principle Investigator |

Mobile number…

सहमति पत्र

मुझे शोधकर्ता द्वारा, जिस उद्देश्य के लिये, मुझे शोधकार्य में भाग लेना है / रक्तदान और ऊतक दान करना है, उसके फायदे और नुकसान बता दिये गये हैं। मैं बिना किसी दबाब के, अपनी इच्छानुसार (लागू पर ✓ करें) ।

☐ इस शोधकार्य में भाग लेने के लिये सहमत हूँ, इस शोधकार्य के लिये सभी प्रकार के परीक्षण, जो मानव जाति के कल्याण के लिये, ज्ञान प्रदान करते हैं, के लिये सहमत हूँ।

☐ इस शोधकार्य के लिये अपना या अपने बच्चो का ..... मि.ली. रक्तदान/ऊतक दान कर रहा हूँ।

☐ शोधकार्य से स्मंबंधित सर्वे में भाग लेने के लिये अपनी सहमति प्रदान करता हूँ

मेरी सहमति प्रत्यक्ष रूप से किसी भी व्यक्तिगत जानकारी के खुलासे के लिये नहीं है। मेरे नमूनों से प्राप्त व्यक्तिगत जानकारी के खुलासे के लिये मेरी अगली अनुमति अनिवार्य है।

मुझे यह जानकारी दे दी गयी है कि कु0 मायावती राजकीय स्नातकोत्तर महाविद्यालय, बादलपुार और इसके शोधकर्ता (प्रधान अन्वेषक/शोध छात्र)..... एवं इनके सहयोगी, किसी भी फायदे के कार्य से पहले, जो मेरे रक्त या ऊतक नमूनों की जानकारी पर आधारित है, मेरी अनुमति लेगें।

दानकर्ता/मरीज के हस्ताक्षर गवाह के हस्ताक्षर

प्रधान अन्वेषक/शोध छात्र के हस्ताक्षर

मोबाईल न.

SOP FOR PROPOSALS RELATED WITH VULNERABLE POPULATIONS. (AS PER ICMR 2017 CHAPTER VI – VULNERABILITY)

In alignment with the ethical standards established by the Indian Council of Medical Research (ICMR) in the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017), particularly Chapter VI: Vulnerability, the Human Ethics Committee (HEC) acknowledges the importance of safeguarding the rights and well-being of vulnerable populations involved in research.

SELECTION OF VULNERABLE AND SPECIAL GROUPS AS RESEARCH PARTICIPANTS

- Vulnerable groups and individuals may have an increased likelihood of incurring additional harm as they may be relatively (or absolutely) incapable of protecting their own interests.
- Characteristics that make individuals vulnerable are legal status – children; clinical conditions – cognitive impairment, unconsciousness; or situational conditions – including but not limited to being economically or socially disadvantaged, (for example, certain ethnic or religious groups, individuals/communities which have hierarchical relationships, institutionalized persons, humanitarian emergencies, language barriers and cultural differences).
- In general, such participants should be included in research only when the research is directly answering the health needs or requirements of the group. On the other hand, vulnerable populations also have an equal right to be included in research so that benefits accruing from the research apply to them as well. This needs careful consideration by researchers as well as the EC.
- The EC should determine vulnerability and ensure that additional safeguards and monitoring mechanisms are established. It should also advise the researcher in this regard. See section 6 (ICMR 2017) for further details.

DEFINITION AND SCOPE

Vulnerable populations include, but are not limited to:

- Children and minors
- Pregnant or lactating women
- Elderly individuals
- Individuals with mental illness or cognitive impairment
- Economically or socially disadvantaged individuals
- Institutionalized persons

- Members of hierarchical or dependent systems (e.g., armed forces, prisoners)
- Tribals, disaster-affected or displaced communities

As stated in Section 6.1 and 6.2 of the ICMR, 2017 guidelines, research involving these groups must adhere to **enhanced protection mechanisms** and **strict ethical scrutiny**.

KEY ETHICAL PRINCIPLES FOR RESEARCH WITH VULNERABLE GROUPS INCLUDE:

- Avoid exploitation (**ICMR 2017,** Section 6.1)
- Ensure **social value and relevance** of the research
- Minimize risk and ensure fair burden-benefit distribution
- Provide **additional protection mechanisms** (**ICMR 2017,** Section 6.2)
- Involve **legally acceptable representatives (LAR)** when autonomy is diminished

STAKEHOLDER RESPONSIBILITIES (REF: TABLE 6.1 OF ICMR GUIDELINES 2017)

Stakeholder	Key Responsibilities
Researchers	Identify vulnerability, justify inclusion, and ensure extra safeguards
Ethics Committees	Critically assess justification, risk minimization, and protection measures for vulnerable participants
Institutions	Ensure training, policies, and mechanisms are in place
Sponsors	Ensure support for protection mechanisms and post-research access/compensation

COMMITTEE DECISION AND SOP DIRECTIVE

In compliance with Chapter VI and as per Table 6.1 of the ICMR Guidelines:

- **The Human Ethics Committee hereby mandates that all research proposals involving vulnerable populations must undergo both initial and continuing review by the full committee.**
- The HEC will not permit approval through expedited review, sub-committees, or delegated authority for such studies.
- This decision has been incorporated into the **Standard Operating Procedures (SOPs)** of the Committee, under the section titled **"Review Procedures for Vulnerable Populations"**, and is effective from the date of this report.

THE **FULL COMMITTEE** SHALL:

- Conduct a thorough assessment of risks, anticipated benefits, and safeguards.
- Require researchers to justify the inclusion of vulnerable groups and describe measures taken to protect them.
- Ensure that **informed consent** is obtained appropriately, involving legally authorized representatives where necessary.
- Monitor the study closely, requesting interim reports or site visits where warranted.

No expedited or sub-committee approval shall be permitted for such proposals. This is in strict accordance with Section 6.2 and the roles of Ethics Committees outlined in Table 6.1 of the ICMR National Ethical Guidelines (2017).

Prepared by, reviewed by, approved by:

Member Secretary
Name: ***Dr. Dinesh C. Sharma***
Designation: Professor & Head
Dept of Zoology
Km. Mayawati Govt. Girls P.G. College,
Badalpur, G.B. Nagar

प्रो.(डॉ.) दिनेश चन्द्र शर्मा
Prof. (Dr.) Dinesh C. Sharma
NET(JRF), M.Phil, Ph.D, FIAES, PHES(I)
विभागाध्यक्ष–जन्तु विज्ञान/ Head-Zoology
कु.मा. राजकीय महिला स्ना. महाविद्यालय, बादलपुर, जी.बी.नगर
K.M. Govt. Girls P.G. College, Badalpur, G.B. Nagar
https://www.kmgcbadalpur.org/

Chairperson
Name: ***Dr. Anshu Gupta***
Designation: Associate Professor
Head, Dept. of Anatomy
S.N. Medical College, Agra

Prof. (Dr.) Anita Rani Rathore
Principal,
Km. Mayawati Govt. Girls P.G. College,
Badalpur, G.B. Nagar

प्राचार्य
कु. मायावती राजकीय महिला
स्नातकोत्तर महाविद्यालय
बादलपुर (गौतमबुद्धनगर)