INSTITUTIONAL ETHICS COMMITTEE
GOVERNMENT MEDICAL COLLEGE, KATHUA
(DEPARTMENT OF PHARMACOLOGY)

Standard Operating Procedures

Effective Date:-5-9-2022
Next review date: - 5-09-2024

The location and business address of the committee:

Institutional Ethics Committee
Government Medical College,
Kathua-184102

INDEX

1. INTRODUCTION OF THE ETHICS COMMITTEE

Institutional Ethics Committee, Government Medical College Kathua constituted for discussion and approval of institutional/ collaborative research projects with respect to safeguard dignity right safety and well being of all research participants and to ensure that the research is carried under prescribed guidelines.

—Institutional Ethics Committee, Government Medical College Kathua is constituted and operates as per ICMR guidelines, Schedule Y and ICH-GCP‖

Head of the Institution Govt. Medical College, Kathua as per the new guidelines has constituted IEC GMC Kathua vide PMC Order Number GMC/PS/Committee/1106 Dated-5/09/2019.

2.BASIC RESPONSIBILITIES OF ETHICS COMMITTEE

- To ensure the competent review and evaluation of all ethical aspects of research projects received in an objective manner.
- To protect the safety, rights and well being of the potential research participants.
- To conduct scientific evaluation and ensure technical appropriateness of the proposed study.
- To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
- To assist in the development and the education of a research community responsive to local health care requirements.
- Creation, developing revising and implementing ethical guidelines (SOPs)

3. SOPS OF INSTITUTIONAL ETHICS COMMITTEE

3.1 Establishing and Constituting the Institutional Ethics Committee

PURPOSE

To establish and constitute the Institutional Ethics Committee for GMC, Kathua as per ICMR Guidelines, Schedule Y and ICH-GCP

RESPONSIBILITY

Principal & Dean (Head of the Institute) is responsible to initiate the process of constitution of Institutional Ethics Committee.

PROCEDURE-

- Principal & Dean will select and nominate the Chairman (from outside the Institute) and member Secretary (from Institute) for IEC, GMC, Kathua.
- IEC will be constituted by the Principal & Dean in consultation with the Chairman.
- Principal & Dean will designate and instruct Chairman of IEC or his representative to conduct the regular proceedings of IEC for the institute
- Principal & Dean will review the function of IEC at regular interval

3.2 Procedure for appointing members for the IEC

PURPOSE

To appoint suitable members for the IEC, GMC, Kathua

RESPONSIBILITY
Principal & Dean (Head of the Institute) and Chairman are responsible for implementing this SOP.

PROCEDURE

Principal & Dean in consultation with chairman will nominate the members of IEC, who have the qualification and experience to review and evaluate the scientific, medical and ethical aspect of proposed study.
The regular members of the committee will include 7- 15 individuals out of which 50% shall be from outside the institute. Current committee is as follows:

1. One chair person outside the institute
2. Member Secretary from parent institute .
3. Twoexperts from basic medical sciences
4. One basic medical scientist from outside institution.
5. Two clinicians from within the institute
6. One social scientist/ representative of non-governmental voluntary agency/ philosopher/ethicist/theologian
7. One legal person
8. One lay person from the community
9. Whenever required the expert person on particular subject would be invited.

3.3 Training of IEC members

PURPOSE

All IEC members are conversant with Guidelines for Research involving Human Subjects

RESPONSIBILITY

A team of trainers chosen for this purpose by Member Secretary will ensure that all members will have to undergo online training for basic clinical research (GCP)and generate certificate before assuming charge as member of IEC.

PROCEDURE

All IEC members will be made conversant with ICMR Guidelines for Research involving Human Subjects 2018, Schedule Y of Drugs and Cosmetics Act and ICH-GCP guidelines

Training schedule for new members of IEC

S.No	Session Topic	Facilitator	Time period
1.	Roles & responsibilities of IEC and its members	Member Secretary	1 hour
2.	Discussion on regulatory guidelines on IEC	IEC member nominated by Member Secretary	2 hours
3.	Interactive session	With at least two members nominated by Member Secretary	2 hours

Additionally Institutional Ethics Committee will hold retraining for all the members of IEC once in 6 months for 2-3 hours on the topics listed in the above table

3.4 Term of appointment, Policy for removal or Resignation/ Replacement of members

PURPOSE

To establish polices for removal or Resignation / Replacement of members

RESPONSIBILITY

Chairman and Member Secretary are responsible for implementing this SOP.

PROCEDURE

Term of appointment Members of IEC will be appointed for period of 2 years initially which could be extended for another term of 2 years. Extension of membership will be based on the recommendation of the Chairman & Member Secretary of IEC.

Policy for removal of member

- A member may be relieved or terminated of his/her membership in case of conduct unbecoming for a member of the Ethics Committee.
- Inability to participate in the meetings on any grounds for more than 3 meetings of IEC.
- The membership shall be reviewed by the dean & chairman, if the member is a regular defaulter.
- If deemed necessary, the IEC may decide to terminate the membership and recommend to the Chairman IEC for necessary action.
- In all such situations/circumstances, member secretary will serve a letter of termination to the member.
- Documentation of the termination will be recorded in the meeting minutes of the next duly constituted IEC meeting and IEC membership circular/roster will be revised.

Resignation / Replacement procedure

The members who have resigned may be replaced at the discretion of the appointing authority for the same.
IEC members who decide to resign must provide the Chairman & member secretary of IEC the written notification of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting.
In case of resignation, chairman & member secretary would appoint a new member, falling in the same category of membership ex. NGO representative with NGO representative.

3.5 Procedure for convening and conducting IEC meetings

PURPOSE

To hold regular IEC meeting

RESPONSIBILITY

Chairman & member secretary are responsible for implementing this SOP

PROCEDURE

- The Member Secretary in consultation with the chairman may convene the IEC meeting once in every three month.
- Additional review meeting can also be held with short notice as and when required in emergency.
- All members will receive notification of meeting schedules in advance.
- A minimum of five persons is required to form the quorum without which a decision regarding the research would not be taken. The quorum would have at least one representative from the following group:

    1. A minimum of five members present in the meeting room.
    2. The quorum should include both medical, non medical or technical or / and non-technical members.*
    3. Minimum one non-affiliated member should be part of the quorum.
    4. Preferably the lay person should be part of the quorum.
    5. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.
    6. No decision is valid without fulfillment of the quorum.

- Minutes of the IEC meetings, all the proceeding and deliberation will be documented.
- Applicant investigator may be invited to present the proposal or elaborate on specific issue.

3.6 Procedure for submission of research project

PURPOSE

To submit a research proposal for review by IEC.

RESPONSIBILITY

All investigators are responsible for implementing this SOP. All research proposals must be submitted in the prescribed application format, duly filled, along with all necessary documents

PROCEDURE

- Project investigator has to submit an application in prescribed format (Annexure 1) along with study protocol & other study related document necessary for review by IEC.
- The following documents at minimum will be reviewed by ethics committee • Trial Protocol (including protocol amendments)
  - Patient Information Sheet, Informed Consent Form and Patient dairies (including updates if any) in English and/or vernacular language.
  - Investigator's Brochure and available safety information.
  - Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose.
  - Principal Investigator's current CV and any document evidencing qualifications and research experience
  - Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.
  - Investigator's Agreement with the Sponsor.
  - Investigator's Undertaking (Appendix VII).
  - Any other documents that ethics committee may require to fulfill its responsibilities.

- All research proposals must be submitted in English language only.
- Application may be submitted to the office of member secretary, IEC GMC Kathua (minimum three hard copies along with electronic of the same) at least 14 days prior to the date of proposed ethics committee meeting.
- Receipt of application will be acknowledged by IEC office. [Form 3]
- Every application will be allotted an IEC registration number to be used for future correspondence.
- No retrospective request for approval will be entertained.
- No research investigator will submit more than 2 research papers in one IEC meeting for clearance.

3.7 Procedure for initial scrutiny of proposal

RESPONSIBILITY

Office of Member Secretary

PROCEDURE

- Every proposal will be collected and complied by the IEC office.
- Academic assistant will verify the proposal for completeness as per check list (Form-1).
- In case of incomplete data, the investigators will be informed by the office after consulting the Member Secretary to make the necessary correction and to resubmit the proposal.

3.8 Procedure for reviewing the research proposals

RESPONSIBILITY

All members of IEC are responsible for implementing this SOP.

Elements of Review

The submitted proposal shall be reviewed both for scientific content and ethical principles.

The committee members shall review the proposal with reference to the following:

a. Scientific design of the study

b. Justification/Rationale of the study

c. Selection criteria for subjects

d. Justification for use of placebo, if any

e. Potential benefits to the study subjects

f. Predictable risks to the study subjects

g. Criteria for discontinuation/withdrawal of subjects

h. Monitoring of serious adverse events

i. Compensation to subjects for participating in the

study

j. Subject recruitment procedures

k. Patient retention activities.

l. Compensation for study related injury

m. Post trial benefits

n. Protection of privacy and confidentiality

o. Statistical analysis

p. Informed consent document in English and regional languages

q. Competence of investigators, supporting staff and infrastructure facility

r. Approval of regulatory authorities wherever applicable

s. To review the research trial periodically

PROCEDURE

- Every proposal will be evaluated by IEC members on ethical issues as per ICMR Guidelines 2018 as amended thereafter, scientific soundness and technical excellence of the proposed research before it is taken up for main IEC interview, on the same study.

  All 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 IEC 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.

Summary of the procedure adopted

1. As per the routine adopted, ***Approval of IEC should follow first before synopsis ofthesis or any research project is submitted by the candidate for approval from board of study committee/University.***

2. Every HOD should ensure that candidate undertaking ***any kind of research on humans(interventional/ non interventional/observational/investigational or any kind of study directly or indirectly dealing with humans)***should submit a copy of protocol along withapplication and electronic version (in pen drive or can e-mail us at **iecgmckathua@gmail.com**) of the same in prescribed Performa, well in advance to **member secretary for IEC approval**.

3. Every candidate appearing before IEC should be directed to submit their presentation in electronic format well in advance to member secretary, which shall be circulated to all worthy members and chairman for reference well in advance.

4. **The Certificate of IEC approval is useful while publishing your valuable research in any of the Indian or International journal of repute and impact factor without producing IEC Number(applicable for all type of studies) and Getting registered in Clinical Trial Registry of ICMR- India quoting clinical trial number (applicable for Only interventional drug trials).**

5. ***The responsibility of not getting prior IEC approval shall otherwise lie with respective heads of department at the time of any ethical audit of the institution.***

6. ***The research protocol need to categorized by the candidates AND PRESENTED ONLY IF FALLS IN CAT A.***
   CATEGORY –A (FULL REVIEW / PRESENTATION REQUIRED): presentation has to be made as per serial number or as decided by IEC
   Drug trials/studies
   Interventional Trials

Surgical or diagnostic procedure trials being carried for the first time in the institution other then the routine protocol
New drug trials
Trials on high risk population
Not falling in cat B & C
CATEGORY –B (EXPEDITED REVIEW/PRESENTATION OPTIONAL /BUT APPLICATION AND SUBMISSION OF PROTOCOL IN PRINT /ELECTRONIC FORMAT REQUIRED FOR RECORD)

Expedited Review Procedures

a. The committee may use expedited review procedure in case of minor changes/ amendments in the previously approved research proposal that appear to involve no more than minimal risk to the study subjects.

b. Under an expedited review procedure, the review may be carried out by the Chairperson of the committee, or by one or more experienced reviewers designed by the chairperson from among the members of the committee. The reviewers may exercise all of the authorities of the committee except that the reviewers may not disapprove the research.

c. The committee will keep all members of the committee informed of these approvals under the expedited review procedure.

d. Only the Chairperson and Member Secretary shall make the decision to allow an expedited review

CATEGORY –C (EXCEMPTION FROM REVIEW & PRESENTATION ONLY APPLICATION REQUIRED)

7. ***It is requested to make arrangement of 5 minutes presentation by each candidate with maximum 8 slides in power point to be presented in front of Institutional Committee on above said date and time, who have submitted proposals for approval.***

8. ***Guide and respected Co-guide can Join The meeting for scientific interaction.***

9. ***Not more than 30 projects shall be consider in one day or as the situation demands***

10. ***Independent Projects as per the same SOP Shall be considered first followed by thesis research protocols.***

11. ***Investigator/Candidate is requested to make and present power point slides of your project proposal which should include following points/guidelines depicted below.***

1. Introduction and Background of the subject
2. Rationale/ Justification of Undertaking the project
3. What new the research/Project is going to contribute to scientific community & Our setup
4. Is your research/project following all basic principal of Bioethics-
   Principles of essentiality
   Research is necessary for the advancement of knowledge-Should add new Information
   Rationale Justification of Research Question
   Principles of precaution and risk minimisation
   Principles of the maximisation of the public interest
   Principles of non-exploitation
   Principles of voluntariness, informed consent and community agreement
   Respect for persons: dignity and rights of each trial participant
   Is there provision for Participants to withdraw at any time?
   Is there any provision to ensure/ Protect Confidentiality
   Is there any provision for Compensation
5. Aims and Objectives
6. Materials and Methods to undertake the project
7. Statistical Methods intend to use
8. Flow chart of your project/CONSORT

3.8 For Vulnerable Groups

The ethics committee will exercise particular care to protect the rights, safety and well being of all vulnerable subjects participating in the study as per Good Clinical Practices for Clinical Research in India;

Effort will be made to ensure that individuals or communities invited for research is selected in such a way that the burdens and benefits of the research are equally distributed.

a. Research on genetics does not lead to racial inequalities;

b. Persons who are economically or socially disadvantaged are not used to benefit those who are better off than them;

c. Rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders is protected.

d. Adequate justification is made for the involvement of subjects such as prisoners, students, subordinates, employees, service personnel etc. who have reduced autonomy as research subjects.

3.9 Procedure for decision making regarding the research Project and communicating the decision of IEC to the Investigator

RESPONSIBILITY

All members of IEC of GMC Kathua

PROCEDURE

- A decision will only be taken when sufficient time has been allowed for review and discussion on application occurred in the absence of investigator from meeting
- Decision will only be taken at meeting where quorum (minimum of five members) is complete
- Decision will only be taken after reviewing complete application with all required documents necessary for proposal (Form-1)
- Decision will arrive with consensus of members; if consensus appears unlikely voting can be resorted to. Decision will be taken in specified format (Document-3)
- A negative decision would always be supported by clearly defined reason.
- The Member Secretary would communicate the decision in writing to the Principal Investigator in prescribed format (Document-4)
- If one of the members has her/his own proposal for review then s/he would withdraw from the IEC while the project is being discussed

4.0 Procedure for documentation & archiving of documents

PURPOSE

To archive the study related documents, proceedings and communications

RESPONSIBILITY

The office of the member secretary is responsible for implementing this SOP

PROCEDURE

- Academic assistant who will help the IEC Member Secretary in executing functions of the IEC, documentation & archiving documents.
- All documents, communication of IEC will be dated, filed & achieved in a secure place.
- Only person who are authorized by chairman of IEC will have access to various documents.
- All documents related to research project will be archived for a minimum period of three years in Institute following completion or termination of project.
  All the agenda & minutes of meeting will be filed & archived

The records shall be made available to relevant statutory authorities upon request.

Document -1: Request letter by Dean to the members

Letter Ref. No:

From
Principal
GMC, Kathua

To
_____
_____
_____

Sub: Constitution of Institute Ethics Committee (Human studies)

Dear Sir

I am pleased to inform you that your are selected for the post of Chairman / Member Secretary / Member of IEC. Kindly send your written acceptance in enclosed format. On recipient of your acceptance, I shall send you the formal appointment letter.

Yours sincerely

Signature

Document-2: Consent letter by members of IEC

From

To
The Principal
GMC Kathua

Sub: Consent to be a member of Institute Ethics Committee (Human Studies)

Reg. Ref: You're Letter No:

Dear Sir,

In response to your letter stated above, I give my consent to become a Chairman / Member Secretary / Member of IEC of GMC, Kathua. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues. I shall not keep any literature or study related documents 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 anybody other than project related personnel

Thanking you

Yours Sincerely

Signature
Date
Name of the member
Department & designation

Document -3: GMCK, IEC Review Letter

Review letter No of IEC—

To,

The meeting of the IEC for the year ____ was held in GMC on ____ under the Chairmanship of _____. Following members at tended the meeting

Name Signature
1.
2.
3.
4.
5.
6.
7.
8.
9.
10.

After the proceeding, the proposals listed for meeting were taken up for discussion. After deliberation the following decisions were arrived

No. of proposal received-
No. of proposals approved_____.proposals approved subject to correction_____

The recommendation made by the committee to each proposal is detailed below:

S.N.	Reg. No. of proposal	Name of Principal investigator	Title of Research Proposal	Recommendation of the committee

Chairman/ Member Secretary
IEC (Human studies)

Document -4: Format for Approval of Ethics Committee

To

Dr.

Dear Dr. _____

The Institutional Ethics Committee reviewed and discussed your application to conduct the clinical trial entitled "……" on …….(date).

The following documents were reviewed:

a. Trial Protocol(including protocol amendments), dated_____ Version no (s)._____
b. Patient Information Sheet and Informed Consent Form (including updates if any) in English and/or vernacular language.
c. Investigator's Brochure, dated_____, Version no._____
d. Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose.
e. Principal Investigator's current CV.

f. Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.

g. Investigator's Agreement with the Sponsor.

h. Investigator's Undertaking (Appendix VII).

The following members of the ethics committee were present at the meeting held on (date, time, place).

_____ Chairman of the Ethics Committee

_____ Member secretary of the Ethics Committee

_____ Name of each member with designation

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

Yours sincerely,

Member Secretary, Ethics Committee.

Form -1
Initial check list to verify completeness of documents submitted

For office use only-

1. Three (for PG dissertation/ Ph.D thesis/ ICMR studentship) copies of proposal for Ethics sub committee
2. Performa completely filled & duly signed by the investigators
3. Consent form 3 for patients in English / Hindi / Local Language
4. Consent form 2 completely filled with all the question answered in complete sentence & simple language
5. In case the research involves a study product (such as a pharmaceutical or device under investigation, an adequate summary of all safety, pharmacological pharmaceutical and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g.: recent investigator's brochure published data, a summary of the product's characteristics); (Product information)
6. Investigator(s) curriculum vitae (updated, signed and dated)
7. Material to be used (including advertisements) for the recruitment of potential research participants;
8. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants;
9. A description of the arrangements for indemnity, if applicable;
10. A description of the arrangements for insurance coverage for research participants, if applicable
11. A statement of agreement to comply with ethical principles set out in relevant guidelines

Form – 2

Acknowledgement Letter

IEC has received research proposal entitled _____
_____
_____
Registration Number of the above research proposal is _____.

_____

Member Secretary

Form-3

Declaration Form

I Dr_____ hereby declare that I will not disclose identity of the research participants any time during or after the study period or during publication.

Signature of Investigator

Annexure -1

Proforma to be submitted to the GMC KathuaInstitute Ethics committee

1. Title of the Project	
2. Name of the chief investigator & department	
3. Name of co-investigator (s) & department	
4. Source of funding	
5. Objectives of study	
6. Justification for conduct of study	
7. Methodology – it should provide detail of number of patients, inclusion criteria, exclusion criteria, control(s), study design	
8. Ethical issue involved in study	
9. Cost involved	
10. Permission from Drug Controller General of India, if applicable	
11. Whether consent form in local language is enclosed	
12. Conflict of interest for any other investigator, if any	
	Signature of investigator

Annexure 2 Members of IEC (Human Research)

1. Dr.Vijay Khajuria -- Chairperson, ex-Prof Pharmacology & Member secretary ethics committee GMC Jammu.
2. Dr.VineetaSawhney – Member Secretary, Professor and HOD Pharmacology, GMC Kathua.
3. Dr. Vishal Tandon- Member, Professor Pharmacology,(ex member IEC GMC Jammu) Basic Scientist.
4. Dr.BadrinathBoughal-- Member, Professor and HOD Medicine, GMC Kathua.
5. Dr. Raj Rishi Sharma-- Member, Professor and HOD Surgery, GMC Kathua.
6. Dr.SanjayKalsotra -- Member, Professor and HOD Anesthesia, GMC Kathua.
7. Dr.Nusrat K. Bhat -- Member, Professor and HOD Pharmacology, GMC Jammu.
8. Dr.MeenakshiRana -- Member, Associate Professor and HOD Gynae&Obst, GMC Kathua.
9. Dr.Yangchen Dolma -- Member, Assistant Professor PSM, GMC Kathua. Statistical Expert.
10. Miss Mala Sharma – Member, Associate law officer, As legal expert
11. Mrs.Kusum Sharma Salaria – Representative of NGO/ Social Scientist.
12. Mr.Jogeshwar Sharma – Layman