

Standard Operating Procedures

Institutional Ethics Committee

(IEC, Human Studies)

2012

**GOVERNMENT MEDICAL COLLEGE,
HALDWANI, NAINITAL**

Preface

After the inception of Medical College, Haldwani in the year 2004-05, the college has made remarkable progress in the field of medical education, research and patient care. The college got recognition from Govt. of India & Medical Council of India for grant of MBBS degree and soon thereafter, college got permission for starting the PG courses (MD/MS) in 10 specialties. In the coming year 2012-13, preparations are on for starting PG courses in five more specialties.

In addition to providing quality tertiary medical care to the patients of this region and imparting quality medical education to the youth of the State, the college is committed to conduct research work both in basic and clinical medical science. The medical college has animal & human Institutional Ethics Committee (IEC) for evaluating all research projects and a sub-committee for the research work to be carried out by the post graduates. The purpose of the IEC (Human studies) is to safeguard the dignity, rights, safety and well being of all actual or potential research participants.

A manual on **Standard Operating Procedure** is being formulated to ensure quality, consistency, reliability and uniformity of the process being followed by Ethics Committee. This SOP will be updated periodically, based on the changing requirement. The efforts made by Dr. Vinita Rawat, Associate Professor in Microbiology for preparing this SOP and Shri Amit Dumka, Deputy Manager E&T, who formatted this manual is highly appreciated.

I am confident that this SOP manual will help all the researchers for preparing the research protocols and ensure smooth functioning of IEC (Human studies).



Dr. N.S. Jyala
Principal & Dean
Govt. Medical College, Haldwani

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Responsibilities of an IEC-

- To protect the dignity, rights and well being of the potential research participants.
- 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

Establishing and Constituting the Institutional Ethics Committee

PURPOSE-

To establish and constitute the Ethics Committee for GMC, Haldwani

RESPONSIBILITY-

Dean (Head of the Institute) is responsible for implementing this SOP.

PROCEDURE-

- Dean will select and nominate the Chairman (outside the Institute) and member Secretary (from Institute) for IEC, GMC, Haldwani
- IEC will be constituted by the Dean in consultation with the Chairman
- Dean will invite the members to join ethics committee by sending the official request letter (Document-1)
- Member will confirm their acceptance to the Dean by providing all the required information for membership (Document-2)
- Dean will designate and instruct Chairman of IEC or his representative to conduct the regular proceedings of IEC for the institute
- Dean will review the function of IEC at regular interval

Procedure for appointing members for the IEC

Purpose-

To appoint suitable members for the IEC, GMC, Haldwani

RESPONSIBILITY-

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

PROCEDURE-

- 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
- **Team will be constituted by following members-**
 1. Three persons from basic medical science area
 2. Three persons from clinical side
 3. One social scientist/ representative of non-governmental voluntary agency
 4. One law person
 5. Whenever required the expert person on particular subject would be called

All IEC members must be conversant with ICMR Guidelines for Research involving Human Subjects 2006, Schedule Y of Drugs and Cosmetics Act and ICH-GCP guidelines.

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 If a regular member fails to attend 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.

Procedure for convening and conducting IEC meetings	
Purpose-	
	To hold regular IEC meeting
Responsibility	
	Chairman & member secretary are responsible for implementing this SOP
Procedure	
	<ul style="list-style-type: none"> ➤ The Member Secretary in consultation with the chairman may convene the IEC meeting once in every four month. ➤ Additional review meeting can also be held with short notice as and when required. ➤ A quorum at such meetings shall consist of the majority of the elected members of the Committee. ➤ A minimum of five persons is required to form the quorum without which a decision regarding the research would not be taken. ➤ 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

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 proposal must be submitted in the prescribed application format, duly filled, along with all necessary documents
Procedure	
	<ul style="list-style-type: none"> ➤ Project investigator has to submit an application in prescribed format (Annex 1 & 2) along with study protocol & other study related document necessary for review by IEC. All research proposals must be submitted in English language only. ➤ Application may be submitted to the office of member secretary, IEC GMC Haldwani. ➤ Receipt of application will be acknowledged by IEC office. [Form 5] ➤ Every application will be allotted an IEC registration number to be used for future correspondence.

Procedure for initial scrutiny of proposal	
Responsibility-	
	Office of Member Secretary
Procedure	
	<ul style="list-style-type: none"> ➤ 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

Procedure for reviewing the research proposals

Responsibility

All members of IEC are responsible for implementing this SOP

Procedure

- Every proposal will be evaluated by IEC members on ethical issues as per ICMR Guidelines 2006 as amended thereafter, scientific soundness and technical excellence of the proposed research, before it is taken up for main IEC interview
- 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.

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

Responsibility

All members of IEC of GMC Haldwani

Procedure

- A decision will only be taken when sufficient time has been allowed for review and discussion of an application 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

Procedure for documentation & archiving of documents	
Purpose	To archive the study related documents, proceedings and communications
Responsibility	The member is responsible for implementing this SOP
Procedure	<ul style="list-style-type: none"> ➤ Deputy Manager (E & T) and Academic assistant who will help the IEC Member Secretary in executing functions of the IEC, documentation & achieving 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 document of related to research project will be achieved for minimum period of three years in Institute following completion or termination of project. ➤ All the agenda & minutes of meeting will be filed & archived

Document -1

Letter Ref. No:

From
Principal
GMC, Haldwani

To

Sub: Constitution of Institute Ethics Committee (Human studies)

Dear Sir

I am pleased to inform you that your name has been selected Chairman / Member Secretary / Member of IEC. Kindly send your written acceptance in enclosed format. On receipt of your acceptance, I shall send you the formal appointment letter.

Yours sincerely

Signature

Document-2

From

To
The Principal
GMC Haldwani

Sub: Consent to be a member of Institute Ethics Committee (Human Studies)- Reg. Ref: Your 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, Haldwani. 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 any body other than project related personnel

Thanking you

Yours Sincerely

Signature

Date

Name of the member

Department & designation

Annx -1

Proforma to be submitted to the GMC Institute Ethics committee for MD/MS students

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

Annx-2

Proforma to be submitted to the GMC Institute Ethics committee for Project

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	

Form-1

Initial check list to verify completeness of documents submitted

For office use only-

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

Document -3

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 attended 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

Human Ethics committee approval

The members of IEC met on _____ at GMC Haldwani and reviewed the Project entitled _____

The IEC after careful deliberation has granted approval to the project.

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

Member secretary

IEC, GMC, Haldwani

Form -2**Information form for patients**

Title of the project	
Name of the investigator	
Purpose of the study	
Procedure/ method of study	
Expected duration of subject participation	
Benefits to be expected from research to the participant	
Any risk expected from study to the participant	
Maintenance of confidentiality of result	
Provision for free treatment for research related injury	
Compensation to the participant for research related injury	
Freedom to withdraw from study at any time during research	
Possible current or future use of biological material & data to be generated from research & if material is likely to be used for some other purpose or be shared with other- should be mentioned	
Patient information sheet must be signed by investigator.	

Form-3

Participant consent form

Participant name

Address –

Title of project –

The detail of study has been provided to me in writing and explained to me in my own language. I confirm that I understood the above study and had opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. I agree not to restrict any use of the data or result that arises from study provided such use is only for scientific purpose(s). I have been given an information sheet giving detail of the study. I fully consent to participant in this study.

Signature of patient & date

Form-4

प्रतिभागी सहमति-पत्र

प्रतिभागी का नाम:

पता:

प्रोजेक्ट का शीर्षक:

इस शोध की विस्तृत जानकारी मुझे लिखित रूप से उपलब्ध करा दी गई है तथा मुझे मेरी भाषा में समझा दी गई है। उक्त शोध की जानकारी से मैं आस्वस्त हूँ तथा मेरे सभी सन्देह दूर हो गये हैं। इस शोध में मेरी प्रतिभागिता स्वैच्छिक है तथा मैं किसी भी समय इससे अलग होने के लिये स्वतन्त्र हूँ। उक्त शोध से प्राप्त प्रदत्तों एवं परिणामों का वैज्ञानिक उद्देश्य के हेतु इस्तेमाल करने पर मैं सहमति प्रदान करता/करती हूँ। उक्त शोध के सम्बन्ध में विस्तृत जानकारी-पत्र मुझे प्राप्त करा दिया गया है। मैं उक्त शोध हेतु पूर्ण रूप से अपनी सहमति प्रदान करता/करती हूँ।

हस्ताक्षर प्रतिभागी

Form – 5

Acknowledgement Letter.

IEC has received research proposal entitled _____

Registration Number of the above research proposal is

_____.

Member Secretary.

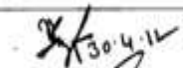
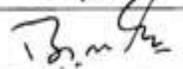


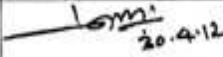
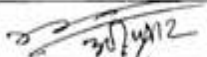
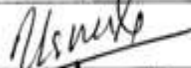
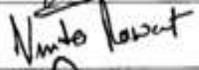
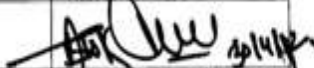
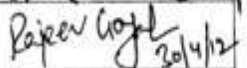
Declaration Form.

I Dr _____ here by 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.

Members of IEC

Members of IEC

Name	Position in committee	Qualification	Signature
Prof. N.S. Jyala	Principal & Dean	MBBS, M,D	 30.4.12
Dr. B, S, Bisht	Chairman	M.Sc, Ph,D	
Dr. C.M.S. Rawat	Member secretary	MBBS,MD	
Shri N.B. Tiwari Ex. Additional Advocate General/ Chief Standing Counsel	Member	L.L.B	
Mr Sher Singh Naulia	Member	MA	
Dr N. Thapliyal	Member	MBBS, M.D	 20.4.12
Dr. K. S. Sahi	Member	MBBS, M.S	 20/4/12
Dr. Urmila Paralia	Member	MBBS,M.D	
Dr Vinita Rawat	Member	MBBS,M.D	
Dr Ashok	Member	MBBS, MD	
Dr Rajeev Goyal	Member	MBBS, MD	 20/4/12