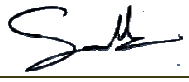
Standard Operating Procedures

Institutional Ethics Committee
(IEC, Human Studies)

GOVERNMENT MEDICAL COLLEGE,
HALDWANI, NAINITAL

Rev. Ver.-1/04/2021
Effective Date : 10-April-2021

Prepared By	
Name	*Prof. Sadhana Awasthi*
Designation	*Member Secretary, IEC*
Sign	
Date	10-April-2021
	Approved By
Name	*Prof. Bhagwan Singh Bisht*
Designation	*Chairperson, IEC*
Sign	
Date	10-April-2021
	Authorized By
Name	*Prof. C.P. Bhaisora*
Designation	*Principal & Dean*
Sign	
Date	10-April-2021

INDEX

1.OBJECTIVES :	
	The objective of this Standard Operating Procedure (SOP) is to ensure quality and consistency in review of clinical research proposals and to contribute to the effective functioning of the Institutional Ethics Committee (IEC) so that a quality and consistent ethical review mechanism for health and biomedical research is put in place for all proposals dealt by the Committee as prescribed by the Ethical guidelines for biomedical research on human subjects and to follow the current ICMR and national ethical guidelines for biomedical research on human subjects.

2.SCOPE:	
	The SOP applies to the review and assessment of all protocols submitted for initial review and approval from the IEC. The specific points in the guidelines attached to the assessment form for initial review must be adequately addressed in the protocol itself and/ or protocol related documents under review. Relevant comments made during discussion and deliberation about a specific protocol should be recorded in the minutes of the meeting. The decision reached by the IEC will be communicated to the PI.

3. ROLE AND RESPONSIBILITY OF IEC:	
	3.1 The basic responsibility of an EC is to ensure protection of the dignity, rights, safety and well-being of the research participants.
	3.2 The EC will ensure ethical conduct of research by the investigator team.
	3.3 The EC is responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.
	3.4 The EC will perform its function through competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations.
	3.5 The EC will ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.
	3.6 The EC will assist in the development and education of the research community in the given institute (including researchers, clinicians, students and

	others), responsive to local healthcare requirements.
	3.7 Responsibilities of members will be clearly defined (details in Table 2.1). The SOPs will be given to EC members at the time of their appointment.
	3.8 The EC Secretariat will support the Member Secretary and Alternate Member Secretary (if applicable) in all their functions and will be trained in documentation and filing procedures under confidentiality agreement.
	3.9 The EC will ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.
	3.10 The EC will review progress reports, final reports and AE/SAE and gives needful suggestions regarding care of the participants and risk minimization procedures, if applicable.
	3.11 The EC will recommend appropriate compensation for research related injury, wherever required.
	3.12 The EC will carry out monitoring visits at study sites as and when needed.
	3.13 The EC will participate in continuing education

	activities in research ethics and get updated on relevant guidelines and regulations.
	3.14 The EC may see that conduct of same/similar research by different investigators from same institution is harmonized. 'Me too' research (replicative) will not be encouraged and submission of same research to different funding agencies will not be accepted.

4. COMPOSITION OF IEC:	
	4.1 ECs will be multi-disciplinary and multi-sectoral in composition. Independence and competence of EC members will be ensure . 4.2 There will be adequate representation of age and gender. 4.3 Preferably 50% of the members will be non-affiliated or from outside the institution. 4.4 The number of members in an EC should preferably be between 7 and 15 and a minimum of five members should be present to meet the quorum requirements. 4.5 The EC will have a balance between medical and non-medical members/technical and non-technical members, depending upon the needs of the institution.

Table 4.1 Composition, affiliations, qualifications, member specific roles and responsibilities of an EC

S. No.	Members of EC	Definition/description
1.	**Chairperson** 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** 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.
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	• 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

	• 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	concerns. • Assess on societal aspects if any.

4.6 The quorum should be as specified in Table 4.2.

Table 4.2 Quorum requirements for EC meetings
1. A minimum of five members present in the meeting room. 2. The quorum will include 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 will be part of the quorum. 5. The quorum for reviewing regulatory clinical trials will be in accordance with current CDSCO requirements. 6. No decision is valid without fulfilment of the quorum **Medical members are clinicians with appropriate medical qualifications. Technical members are persons with qualifications related to a particular branch in which the study is conducted, for example social sciences.*

4.7 So as to maintain independence, the head of the institution will not be part of the EC but will act as an appellate authority to appoint the committee or to handle disputes.
4.8 The Chairperson and Member Secretary could have dual roles in the ethics committee. They could fulfill a role based on their qualifications (such as that of clinician, legal expert, basic scientist, social scientist, lay person etc.) in addition to taking on the role of Chairperson or Member Secretary.

4.9 The EC can also have a set of alternate members who can be invited as members with decision-making powers to meet the quorum requirements. These members have the same TORs as regular members and can attend meetings in the absence of regular members.
4.10 The EC can maintain a panel of subject experts who are consulted for their subject expertise, for instance, a paediatrician for research in children, a cardiologist for research on heart disorders, etc. They may be invited to attend the meeting to give an expert opinion on a specific proposal but will not have decision making power/voting rights.
4.11 The EC may invite subject experts as independent consultants or include a representative from a specific patient group as a member of the EC or special invitee, for opinion on a specific proposal, for example HIV, genetic disorders, or cancer, with appropriate decision making power.
4.12 As far as possible a separate scientific committee will priorly also review proposal before it is referred to EC. EC can raise scientific queries besides ethical ones as both good science and ethics are important to ensure quality of research and participant protection.

5. Terms of reference for EC members	
	5. The head of the institution will appoint all EC members, including the Chairperson.
	5.1. The appointment letter issued to all members will specify the TORs. The letter issued by the head of the institution will include, at the minimum, the following: 5.1.1. Role and responsibility of the member in the committee 5.1.2. Duration of appointment 5.1.3. Conditions of appointment
	6. Members of IEC will be appointed for period of 3 years initially which could be extended for another term of 3 years. Extension of membership will be based on the recommendation of the Chairman & Member Secretary of IEC.
	7. EC members will be given a reasonable honorarium for attendance at the meeting.
	8. **Policy for removal of member-** Failure to attend more than **3 consecutive meetings of IEC**. The member secretary will serve a letter of termination to the member after recommendation from IEC. Documentation of the termination will be recorded in the meeting minutes of the next duly constituted IEC meeting and IEC membership will be revised.
	9. **Resignation / Replacement procedure-** Prior

	written notification of 1month from the date of resignation is required. The head of institution will replace the member from same category e.g. Lay person with a layperson.
	10. Members to be appointed on the EC will be willing to fulfill the EC requirements as given in Table 5.1.

Table 5.1 Requirements for EC members

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

6. TRAINING OF EC MEMBERS:	
	6.1 Members will be trained in human research protection, EC functions and SOPs, and will be conversant with ethical guidelines, GCP guidelines (if applicable) and relevant regulations of the country.
	6.2 EC members will undergo initial and continuing training in human research protection, applicable EC SOPs and related regulatory requirements. All trainings will be documented.
	6.3 Any change in the relevant guidelines or regulatory requirements will be brought to the attention of all EC members.
	6.4 EC members will be aware of local, social and cultural norms and emerging ethical issues.

7. PROCEDURE FOR CONVENING AND CONDUCTING IEC MEETINGS:	
	7.1 The Member Secretary in consultation with the chairman may convene the IEC meeting once in every three months.
	7.2 Additional review meeting can also be held with short notice as and when required.
	7.3 The Member Secretary will be responsible for preparing Minutes of the IEC meetings, all documenting the proceeding and deliberation, record keeping.
	7.4 The Principal investigator/ co- investigator will be invited to present the proposal in IEC meeting. In case of PG thesis presentation or PG/ UG research the Supervisor/ co- supervisor must be present in IEC meeting.

8. DETAILS OF DOCUMENTS TO BE SUBMITTED FOR EC REVIEW:	
	i. Cover letter to the Member Secretary(Annexure 1)
	ii. Application form for initial review (Annexure 2)
	iii. Brief CV of all Investigators (Annexure 3)
	iv. Good Clinical Practice (GCP) training of investigators in last 3 years
	v. Copy of the detailed protocol(Annexure 4)
	vi. Participant information sheet (Annexure 5)
	vii. Informed Consent Form (English and hindi) (Annexure 6&7)
	iii. Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs)

9. SOP FOR RESEARCH AMONG VULNERABLE POPULATION:	
	9.1. For women of reproductive age group:
	9.1.1. If women in the reproductive age are to be recruited for clinical trial/ intervention studies, they will be informed of the potential risk to the foetus if they become pregnant. They will be asked to use an effective contraceptive method and be told about the options available in case of failure of contraception.
	9.1.2. A woman who becomes pregnant will not automatically be removed from the study when there is no evidence showing potential harm to the foetus. The matter will be carefully reviewed and she will be offered the option to withdraw or continue. In case the woman opts for continued participation, researchers and sponsors must adequately monitor and offer support to the woman for as long as necessary.
	9.2. For children:
	9.2.1. Research will be conducted in child-friendly settings, in the presence of parent(s) and where child participants can obtain adequate medical and psychological support.
	9.2.2. Consent of the parent/LAR will be required

	9.2.3. In addition to consent from parents/LARs, verbal/oral or written assent, will be obtained from children of 7–18 years of age.
	9.3. For sexual minorities and sex workers:
	9.3.1. Protection of their dignity and provision of quality healthcare under these circumstances will be well addressed before the proposal is finalized.
	9.4. For tribal population:
	9.4.1. Research will provide benefits in terms of specific therapeutic, diagnostic and preventive nature to the tribal population.
	9.4.2. Due approval from competent administrative authorities, like the tribal welfare commissioner or district collector, will be taken before entering tribal areas.
	9.4.3. Informed consent will be taken in consultation with community elders and persons who know the local language/dialect of the tribal population and in the presence of appropriate witnesses apart from individual consent.
10. ADMINISTRATION AND MANAGEMENT:	
	10.1. Principal office will serve as secretariat for the EC for maintaining safe archival of records and conduct of

	meeting.
	10.2. Principal/ dean will allocate reasonable funds for smooth functioning of the EC in the research proposal in consultation with the community

11. Submission and review procedures:	
	1. Researchers will submit research proposals as soft and hard copies (03) to the Secretariat for review in the prescribed format and required documents as per list given above.
	2. Receipt of application will be acknowledged by IEC office. [Annexure 8]
	3. Every application will be allotted an IEC registration number to be used for future correspondence.
	4. The Member Secretary/Secretariat shall screen the proposals for their completeness as per check list (Annexure 9) and depending on the risk involved categorize them into three types, namely, exemption from review, expedited review, and full committee review.
	5. 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
	6. A researcher cannot decide that her/his proposal falls in the exempted, expedited or full review category. All research proposals must be submitted to the EC. The decision on the type of review required rests with the EC and will be

	decided on a case-to-case basis. Researchers can approach the EC with appropriate justification for the proposal to be considered as exempt, expedited or if waiver of consent is requested.
	7. Expedited review will be conducted by sub-committee members designated by Chairman in consultation with Member, Secretary.
	8. Approval granted through expedited review will be ratified at the next full committee meeting.
	9. EC members will be given 1 week to review the proposal and related documents, except in the case of expedited review before scheduled EC meeting.
	10. If a member has declared a COI for a proposal then this will be submitted in writing to the Chairperson before beginning the meeting and will be recorded in the minutes.
	11. The member who has declared COI will withdraw from the EC meeting (leave the room) while the research proposal is being discussed upon. This will be minuted and the quorum rechecked.
	12. EC will evaluate the protocol based on issues

	related to Social values, Scientific design and conduct of the study, Benefit-risk assessment, Selection of the study population and recruitment of research participants, Payment for participation, Protection of research participants' privacy and confidentiality, Community considerations, Qualifications of researchers and adequacy assessment of study sites, Disclosure or declaration of potential COI, Plans for medical management and compensation for study related injury, Review of the informed consent process.
	13. The Member Secretary would communicate the decision in writing to the Principal Investigator in prescribed format (Annexure-10)

12. PROCEDURE FOR DOCUMENTATION & ARCHIVING OF DOCUMENTS:	
	1. Deputy Manager (E & T) and Academic assistant who will help the IEC Member Secretary in executing functions of the IEC, documentation & archiving documents.
	2. All documents, communication of IEC will be dated, filed & achieved in a secure place.
	3. Only person who are authorized by chairman of IEC will have access to various documents.
	4. All document of related to research project will be archived for minimum period of three years in Institute following completion or termination of project.
	5. All the agenda & minutes of meeting will be filed & archived

13. **PROCEDURE FOR MONITORING & PREVENTING CONFLICT OF INTEREST**	
	11.1. Research institutions: 11.1.1. Monitor the research or check research results for accuracy and objectivity. 11.1.2. Will not interfere in the functioning and decision making of the EC.
	11.2. Researchers: 11.2.1. Ensuring that documents submitted to the EC include disclosure of COI (financial or nonfinancial).
	11.3. ECs: 11.3.1. Will evaluate each study in light of any disclosed COI and ensure appropriate action is taken to mitigate this. 11.3.2. Members will disclose their own COI and will withdraw themselves from reviewing or decision making on protocols related to their COI. 11.3.3. Will make appropriate suggestions for management, if COI is detected at the institutional or researcher level.

14. **ADMINISTRATION AND MANAGEMENT:**	
	11.1 Principal office will serve as secretariat for the EC for maintaining safe archival of records and conduct of meeting.
	11.2 Principal/ dean will allocate reasonable funds for smooth functioning of the EC.

15. BIBLIOGRAPHY:
13.1 National Ethical guidelines for biomedical and health research involving human participants. Indian Council of Medical Rsearch 2017. *(Available at: http://ncdirindia.org/Ethics/Download/ICMR_Guidelines_2017.pdf)*
13.2 Good Clinical Practices for Clinical Research in India by Central Drugs Standard Control Organization, New Delhi, *(Available at: http://www.cdsco.nic.in/html/GCP1.html)*

14. ANNEXURES:

Annexures

Annexure- 1

Cover letter

To
The Member Secretary
Institutional Ethics Committee
Government Medical College Haldwani
Uttarakhand.

Date –

Sub: Submission of research proposal for ethical approval

Sir/ Ma'am

A research proposal is enclosed with this letter for your approval titled "_____". All necessary documents and required information is made available with the proposal.

I am hopeful of getting your approval to do this research work.

Thank you

Name of PI: _____

Signature: _____

Designation & department: _____

Application form for initial review

SECTION A - BASIC INFORMATION

a) Name of Principal Investigator:
b) Department/Designation:
c) Type of review requested:
i. Exemption from review ii. Expedited review iii. Full committee review

d) Title of the study:

_____
_____
_____
_____

e) Details of Investigators:

Name	Designation, department	Email id, Mob. No.
Principal investigator/ MD student		
Co- investigator/ Supervisor/ Co- Supervisor		

f) Number of studies where applicant is a:
i. Principal investigator at the time of study ____
ii. Co- investigator at the time of study ____

g) Duration of the study: ____
h) Funding & budget details (if applicable): _____

SECTION B - RESEARCH RELATED INFORMATION

i) Lay summary of research (300 words)

_____
_____
_____
_____
_____
_____

j) Type of study:

Basic Sciences____Clinical_____ Cross Sectional_____

Retrospective_____ Prospective _____ Epidemiological/ Public Health_____ Case Control_____
Cohort_____ Qualitative_____Quantitative _____ Socio-behavioural _____ Systematic Review
_____ Biological samples/ Data___ Mixed Method_____ Any others *(Specify)*_____

k) Sample size/ number of participants *(as applicable)* _____

l) Justification for the sample size chosen (100 words)

_____
_____
_____

m) Is there an external laboratory/outsourcing involved for investigations?

Yes ____ No ___ NA _____

n) How was the scientific quality of the study assessed?

Independent external review _____ Review by sponsor/Funder _____ Review within PI's institution ____ Review within multi-centre research group _____

No review _____

o) Date of review:

p) Comments of scientific committee, if any (100 words)

_____
_____
____

SECTION C: PARTICIPANT RELATED INFORMATION

q) Type of participants in the study:
Healthy volunteers_____ Patients _____ Vulnerable persons/ Special groups_____

Others (Specify) _____

r) Who will do the recruitment? _____
s) recruitment methods used _____
t) Will there be vulnerable persons / special groups involved ?
Yes ___ No ____ NA ____

u) If yes, type of vulnerable persons / special groups
Children under 18 yrs _____ Pregnant or lactating women _____

Differently abled (Mental/Physical) _____ Employees/Students/Nurses/Staff

_____ Elderly _____ Institutionalized _____ Economically and socially disadvantaged
_____ Refugees/Migrants/Homeless _____ Terminally ill (stigmatized or rare diseases)
_____ Any other (Specify): ____

v) Are there any additional safeguards to protect researchparticipants?
_____

w) Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes ____ No _____

If yes, categorize the level of risk:

Less than Minimal risk _____ Minimal risk _____ Minor increase over minimal risk or low risk _____ More than minimal risk or high risk _____

x) What are the potential benefits (participant; society/community; For improvement in science) from the study? _____
y) Type of consent:
Signed consent _____Verbal/Oral consent _____Witnessed consent _____ Audio-Video (AV) consent _____Consent from LAR (If so, specify from whom) _____

Verbal assent from minor (7-12 yrs) along with parental consent _____

Written assent from minor (13-18 yrs) along with parental consent _____

For children<7 yrs parental/LAR consent _____

Other _____

(specify)

z) Who will obtain the informed consent?
PI/ Co- I _____ Nurse/ Counselor _____ Research Staff _____ Other (*Specify)* _____

SECTION D: DECLARATION AND CHECKLIST

DECLARATION (Please tick as applicable)	
☐	I/We certify that the information provided in this application is complete and correct.
☐	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
☐	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulations and guidelines including responsible.
☐	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
☐	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	If applicable, I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
☐	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports (if required) and a final report and also participate in any audit of the study if needed.
☐	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
☐	I/We will protect the privacy of participants and assure safety and confidentiality of study data and biological samples.
☐	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
☐	I/We have the following conflict of interest (PI/Co-PI): 1. ☐ 2. ☐
☐	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI: ☐	Signature:		Click here to enter a date.
Name of Co-PI:	Signature:		Click here to enter a date.
Name of Guide:	Signature:		Click here to enter a date.
Name of HOD:	Signature:		Click here to enter a date.

Annexure 3

Format for Curriculum Vitae for Investigators

Name:	
Present affiliation*(Job title, department, and organisation)***:**	
Address*(Full work address)***:**	
Telephone number:	**Email address:**
Qualifications:	
Professional registration *(Name of body, registration number and date of registration)***:**	
Previous and other affiliations*(Include previous affiliations in the last 5 years and other current affiliations)***:**	
Projects undertaken in the last 5 years:	

Relevant research training/experience in the area:	
Relevant publications *(Give references to all relevant publications in the last five years)*:	
Signature	**Date:** Click here to enter a date.

FORMAT FOR PROTOCOL		
1.	The face page carrying the title of the proposal with signatures of the investigators	
2.	Background	
3.	Rationale of study	
4.	Aims & Objectives	
5.	Methodology- sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded, etc.), types of data collection, intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures, if any, duration of the study; procedure for seeking and obtaining informed consent, plan for statistical analysis of the study; plan to maintain the privacy and confidentiality of the study participants, ethical considerations and safeguards for protection of participants.	
6.	References	

Annexure 5

Participant information sheet

Title of the project	
Name of the investigator	
Purpose of the study	
Procedure/ method of study	**Study design**: **Sample unit –** **Sample size-** **Inclusion Criteria –** **Exclusion Criteria** – **Study Duration**
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	
Signature of Principal investigator	

Annexure 6

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 participate in this study.

Signature of Participant

Date:

Annexure 7

<u>प्रतिभागी सहमति-पत्र</u>

<u>प्रतिभागीकानाम-</u>

<u>पता-</u>

<u>शोधकाशीर्षक</u> :

इस शोध की विस्तृत जानकारी मुझे **लिखित** रूप से उपलब्ध करा दी गयी है तथा मुझे मेरी भाषा में समझा दी गयी है।उक्त शोध की जानकारी से में आश्वस्त हूँ तथा मेरे सभी संदेह दूर हो गए हैं। इस शोध में मैं) अथवा मेरे पुत्र/पुत्री/ पत्नी/पति एवं संबंधी की(प्रतिभागिता स्वैच्छिक है तथा मैं किसी भी समय इससे अलग होने के लिए स्वतंत्र हूँ। उक्त शोध से प्राप्त तथ्यों एवं परिणामों का वैज्ञानिक उद्देश्य हेतु **इस्तेमाल** करने पर मैं सहमति प्रदान करता /करती हूँ। **उक्तशोध** के संबंध में विस्तृत जानकारी-पत्र मुझे प्राप्त करा दिया गया है। मैं उक्त शोध हेतु पूर्ण रूप से अपनी सहमति प्रदान करता/करती हूँ।

हस्ताक्षरप्रतिभागी

Annexure 8

Acknowledgement Letter.

IEC has received research proposal entitled _____

_____

_

_____

_

Registration Number of the above research proposal is

_____.

_____

Member Secretary.

Annexure 9

Checklist for documents needed for reviews

CHECKLIST						
S.No	**Items**	**Yes**	**No**	**NA**	**Enclosure No.**	**EC Remarks(If applicable)**
ADMINISTRATIVE REQUIREMENTS						
1.	Cover letter	☐	☐	☐		
2.	Brief CV of all Investigators	☐	☐	☐		
3.	Good Clinical Practice (GCP) training of investigators in last 3 years	☐	☐	☐		
4.	Approval of Scientific Committee	☐	☐	☐		
5.	EC clearance of other centers*	☐	☐	☐		
6.	Agreement between collaborating partners*	☐	☐	☐		
7.	MTA between collaborating partners*	☐	☐	☐		
8.	Insurance policy/certificate	☐	☐	☐		
9.	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	☐	☐	☐		
10.	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐	☐		
11.	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and	☐	☐	☐		

	modification(s) to protocol					
PROPOSAL RELATED						
12.	Copy of the detailed protocol[11]	☐	☐	☐		
13.	Investigators Brochure (If applicable for drug/biologicals/device trials)	☐	☐	☐		
14.	Participant Information Sheet(PIS) and Informed Consent Form (ICF)(English and translated)	☐	☐	☐		
15.	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
16.	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐	☐		
17.	Advertisement/material to recruit participants (fliers, posters etc)	☐	☐	☐		

PERMISSION FROM GOVERNING AUTHORITIES						
	Other Registration/ permissions	**Required**	**Not required**	**Received**	**Applied dd/mm/yy**	**EC Remarks**
18.	CTRI	☐	☐	☐	Enter date	
19.	DCGI	☐	☐	☐	Enter date	
20.	HMSC	☐	☐	☐	Enter date	
21.	NAC-SCRT	☐	☐	☐	Enter date	
22.	ICSCR	☐	☐	☐	Enter date	
23.	RCGM	☐	☐	☐	Enter date	

24.	GEAC	☐	☐	☐	Enter date	
25.	BARC	☐	☐	☐	Enter date	
26.	Tribal Board	☐	☐	☐	Enter date	
27.	Others (Specify)	☐	☐	☐	Enter date	

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY						
	Item	**YES**	**NO**	**NA**	**Enclosure no.**	**EC remarks**
28.		☐	☐	☐		
29.		☐	☐	☐		

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