INDIRAGANDHIMEDICALCOLLEGE

SHIMLA

SCHEDULEOFPROCEDURE (SOP)

INSTITUTIONALETHICSCOMMITTEE

StandardOperatingProcedures

InstitutionalEthicsCommittee
IndiraGandhiMedicalCollegeShimla

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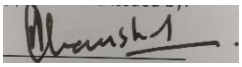

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1. PURPOSE

a. **ToestablishandconstituteInstitutionalethicscommittee**(IEC),IGMCSHIMLA

2. SCOPE

a. ApplicabletoIGMCShimla

3. RESPONSIBILITY

a. Principal,IGMCShimlaisresponsibleforimplementingtheSOP

4. PROCEDURE

Principal,IGMCwillproposethechairmanandmemberSecretaryfor IEC

Chairman&MemberSecretarywillconfirmtheiracceptancetotheprincipalbyprovidingallthe required information for membership **(**Document 2)

The Principal will ensure that the IEC is established in accordance with the applicable laws and regulationsofthestate,countryandinaccordance withthevalueandprinciplesofcommunitiesthey serve (Document 1)

Principal will designate and instruct Chairman of IEC to conduct regular proceedings of IEC for the institute.

Atregularintervals,Principalwillreviewthe functioningof IEC.

A Subcommittee will be formed from the member of the IEC which will be responsible for the approval of protocols of the MD/MS/MCH/DM and research project of MBBS students on the recommendation of protocol committee nominated by principal IGMC Shimla.

SOP.2.

ESTABLISHINGANDCONSTITUTING THEINSTITUTIONALETHICSCOMMITTEE

1. PURPOSE

ToappointsuitablemembersfortheIEC,IGMCShimla

2. SCOPE

ApplicabletoIGMCShimla.

3. RESPONSIBILITY

Principal,IGMCShimlaandChairmanareresponsibleforimplementingtheSOP

4. PROCEDURE

Principal in consultation with the Chairman will propose the members of IEC, who have the qualification and experience as per GCP guidelines of CDSCO and New Drugs and Clinical Trials Rules, 2019 & send them to secretary health & family welfare for proper orders.

Whenneeded,IECwillinvitesubjectexpertstoofferthеirviews.

TheappointmentofanIEC memberwillbe for3 years.

During this term principal can recommend disqualification of any member if, the contribution is not adequate and/or there is longperiod of member's non availability and send the case to Secretary, Health & Family Welfare Government of Himachal Pradesh for proper orders.

Member will have theright to discontinue from membership of IEC aftergiving writtennotice at least one month in advance.

4.6. Principal can propose replacement of the member secretary & chairman of IEC as and when required.

Each member is required to sign the declaration and confidentiality agreement regarding IEC activities (Document -2)

PrincipalcannominateIECmember toundergoorientationprogram in nationalandinternational developments in ethics from time to time

A member nominated from the faculty of IGMC Shimla ceases to be a member from the date of his/her superannuation.

In case of any study involving vulnerable population like HIV, Females, appropriate persons fromthevulnerablepopulationwillbeinvitedasmembertosafeguardtheirinterest.

SOP.3.

ROLESANDRESPONSIBILITIESOFCHAIRPERSON,MEMBERSECRETARY AND ETHICS COMMITTEE MEMBERS

1. PURPOSE

Rolesandresponsibilityofethicscommitteemembers.

2. SCOPE

ApplicabletoIGMCShimla

3. RESPONSIBILITY

TheChairmanandMemberSecretaryareresponsibleforimplementingthisSOP

4. PROCEDURE

The Member Secretary in consultation with the Chairman will convene the IEC meeting once in every three to four months.

Additional review meetings will also be held at short notice as and when required. Meetings will be planned in accordance with the work load.

All the IEC meetings will be held regularly on scheduled date that are announced and notified in advance.

All the proposals will be received at least three weeks before the meeting, checked for completeness initially by the office clerk, subsequently by the member secretary (through a nominated person) using the evaluation form (**Form III**)

Members will be given not less than 10 days' time in advance to review study proposals and the relevant documents.

Minutesofthe IECmeetings,alltheproceedingsanddeliberationwillbedocumented.

Signatures of the Chairman and the Member Secretary & all present members will be obtainedon the minutes of the meeting document. The minutes will be circulated to all guides /HOD in caseof student/thesis protocols.

Applicant, sponsor or investigator 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 applicable confidentiality agreement. They will not have a role in decision making.

Before the newly constituted IEC members take charge they will be invited to attend and undergo a workshop to make them well versant with the **provisions of Institutional Ethics Committee, GCP guidelines (CDSCO) and New Drugs and Clinical Trials Rules, 2019** and as amended from time to time. The members will also be apprised of the recent amendments in these guidelines during the IEC meetings and by holding workshops/ seminars from time to time.

RolesandResponsibilitiesofChairpersonof ethicscommittee:

1. Toconductmeetingsandtobeaccountablefor efficientfunctioningofthe committee
2. Toensureactiveparticipation ofall membersin alldiscussions and deliberations
3. Seekconflictofinterest frommembersandensure quorumandfairdecision making
4. Handlingofcomplaintsagainstinvestigators,IECmembers,conflictofinterestissuesand requests for use of IEC data
5. Toratifytheminutesof previous meetings
6. Toreviewseriousadverseeventswith causality assessment
7. Isthefinalauthorityoftheethicscommitteetotakeanydecisionondisqualificationofa member and recommend his/her termination to the head of the institution
8. Isthe approvalauthorityforSOPsof ethicscommittee
9. ResponsibleformakinganycommunicationsonbehalfoftheethicscommitteetoCDSCO/DCGI and any other regulatory bodies.

RolesandResponsibilitiesofMemberSecretaryofethicscommittee:

1. Toorganizeaneffectiveandefficientprocedureforreceiving,preparing,circulatingand maintaining each proposal for review
2. Toschedule IECmeetings,preparetheagendaandminutes.
3. ToorganizeIECdocumentation,communicationandarchival
4. ToarrangefortrainingofIECsecretariatandmembers
5. ToensurethatSOPsareupdatedasandwhen required
6. ToensureadherenceofIECfunctioningasperSOPs
7. Topreparefor and respondto audits and inspections
8. ToEnsurecompletenessofdocumentationatthetimeofreceiptofprotocols,andtimely inclusion in the agenda for IEC review.
9. Toassessthe needforexemption fromreview,expedited revieworfull review

RolesandResponsibilitiesofMembersofethicscommittee:

1. All members are expected to review the research proposals and attend the ethics committeemeetings, and participate in the discussions and deliberations
2. Toreviewtherevisedsubmissions,additionalsubmissions,progressreportsandfinalreports
3. Toreviewthe reportsof serious adverseevents,andrecommendappropriate actions
4. Tocarryoutmonitoring visitsatstudysitesasandwhen needed
5. Tomaintainconfidentiality ofthedocumentsanddeliberationsofethicscommitteemeetings
6. Todeclareconflictofinterestifany,totheChairperson
7. Toparticipateincontinuingeducationactivitiesinresearchethicsandgetupdatedonrelevant guidelines and regulations.

SOP.4.

GUIDELINESFORINITIALSUBMISSIONOFPROPOSALSFORREVIEW BY INSTITUTIONAL ETHICS COMMITTEE

1. PURPOSE

Tosetinitialsubmissionproceduresfor proposalreview byIEC.

2. SCOPE

Applicableto**PrincipalInvestigators**from IGMCShimla

3. RESPONSIBILITY

All investigators are responsible for implementing this SOP. Every protocol or amendmentsubmitted for review to IEC 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. Proposals may be submitted for review and after the approval, fee (as applicable) needs to be submitted.

4. PROCEDURE

The Project Investigator has to submit an application in a prescribed format along with study protocol and other study related documents necessary for review of the IEC {**Form IA**}. Allresearch proposals must besubmittedin English languageonly. For clinical trials theproposal has to be sent as per Performa {**Form II**}. For MD/MS/DM/MCH/PhD candidates (for Thesis protocols or Dissertation protocols) /MBBS student projects {**Form IB**}

Application can be submitted to the office of the Member Secretary, IEC IGMC Shimla on any working day.

All the proposals and documents must be submitted at least three weeks in advance from the scheduled date of IEC meeting.

Ten copies of study proposals (with all the documents) must be submitted for Regular Ethics Committee review along with application form duly signed and dated by the investigator(s). A soft copy of the proposal must also be submitted on the email id of IEC.

Receiptoftheapplicationwillbeacknowledgedbythe IECoffice.

4.6. Every application will be allotted an IEC registration number to be used for all future correspondence and reference.

Everyresearchproposal willhavetopayafee as under

a. Fordrug trials asum of Rs.10,000 /-(Ten thousand only) per project.
b. For human studies other than drug trials a sum of Rs. 5000/-(Five thousand only) has to be paid if the project has been funded by any internal or external agencies.

The fee to be paid in the form of a demand draft payable to Member Secretary Institutional Ethics Committee, IGMC Shimla.

There will however be no fees for the thesis protocols of MD/MS, DM/MCH and projects of MBBS student of this institution.

SOP.5.

PROCEDURESFORCHECKINGRESEARCHPROPOSALSBYOFFICEOFMEMBER SECRETARY

1. PURPOSE

To**checktheresearchproposals**submittedbytheinvestigatorsforcompleteness.

2. SCOPE

ApplicabletoOfficeofMemberSecretaryIGMCShimla.

3. RESPONSIBILITY

The**officeof MemberSecretary**isresponsiblefor implementingthis SOP.

4. PROCEDURE

Everyproposalwill becollected and compiledbytheInstitutional EthicsCommittee office.

An office staff nominated by the member secretary will verify the proposals for completeness as per the checklist.

In case of incomplete data, the investigators will be informed by the office after consulting theMember Secretary to the make the necessary corrections and to resubmit.

Thesupporting staffavailable tothe Ethicscommitteewill be

- Clerk(RecordKeeper) 1No.
- DataEntry Operator 1 No.
- Class IV 1 No.

TheofficeofMember-SecretaryIECwillbelocatedinthepremisesofAcademicSection, Principal Office, IGMC Shimla.

SOP.6.

ELEMENTSOF REVIEW OF PROPOSALSBY INSTITUTIONALETHICS COMMITTEE

1. PURPOSE

To**review theresearchproposals**submittedbytheinvestigatorsbothscientificallyandethically.

2. SCOPE

ApplicabletoIGMCShimla

3. RESPONSIBILITY

All**membersofIEC**areresponsibleforimplementingthis SOP.

4. PROCEDURE

The Member Secretary is responsible for **categorizing the protocols for review as full review, expedited review and exempted from review as per ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Subjects 2017**. The suggestions/guidance of the Chairperson is taken whenever necessary.

All research proposals presenting more than minimal risk that are not covered under exempt or expedited review will be subjected to full committee review.

Every proposal will be sent not less than 10 days before the meeting to all members of IEC. They will evaluate them on ethical issues, scientific soundness and technical excellence of the proposed research, before it is taken up for main IEC review (As per checklist in **Form III**)

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 review will be done as per the guidelines of **ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Subjects 2017, New Drugs and Clinical Trials Rules 2019and GCP guidelines**.

The IEC review will be done through formal meetings and will not resort to decision through circulation of proposal.

Expertopinion ofadditional memberswould beobtained ifnecessary.

SOP.7.

GUIDELINESFOREXPEDITEDREVIEWANDAPPROVALOFRESEARCHPROPOSALS

1. **PURPOSE**
   Toprovide**expeditedreviewandapproval**ofaresearchproposal

2. **SCOPE**
   ApplicabletothemembersofIECof IGMCShimla.

3. **RESPONSIBILITY**

   All**membersofEthicsSub-Committee**areresponsibleforimplementingthisSOP.

4. **PROCEDURE**

   IECwillreceiveandconsidertheproposalsforexpeditedreviewandapprovalforthe studies having/involving:

i. Minor deviations from originally approved research causing no risk or minimal risk to trial participants.
ii. Modifications or amendment to approved protocol including administrative changes or correction of typographical errors and change in investigator(s)
iii. Research involving non-identifiable specimen and human tissue from sources likeblood banks, tissue banks, left over clinical samples
iv. Researchinvolvingclinicaldocumentationmaterialswhicharenon-identifiable (data, documents, records)
v. Progress/annual reports where there is no additional risk e.g. activity limited to data analysis
vi. The protocols of MD/MS/MCH/DM & research projects of MBBS students if they do not include drug trial & any potential risk to study subjects.
vii. All other proposals which do not comply with the above criteria will be reviewed in the Regular Ethics Committee meeting.

   AllexpeditedapprovalswillbegiveninameetingoftheSub-Committeecomprisingof Chairperson or member secretary and 1-2 designated members.

   Decision taken by the Sub-Committee on expedited approvals will be put up before the IEC at its next regular meeting for ratification.

SOP.8.

PROCEDURE FOR REVIEW OF CLINICAL TRIALS (CONDUCT/ RECRUITMENT, INFORMED CONSENT, REVIEW OF ONGOING STUDIES, DEVIATION AND VIOLATIONS, SEVERE ADVERSE EVENTS AND PAYMENT OF COMPENSATION).

1. PURPOSE

To provide procedures for Review of Clinical Trials (Conduct & recruitment, Informed consent, review of ongoing studies, deviation and violations and SAEs) by IEC.

2. SCOPE

Applicableto**PrincipalInvestigators**from IGMCShimla

3. RESPONSIBILITY

AllinvestigatorsareresponsibleforimplementingthisSOP.Everyprotocoloramendmentsubmittedfor review to IEC 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.

4. PROCEDURE

The Project Investigator has to submit an application in a prescribed format along with study protocol and other study related documents necessary for review of the IEC {**Form II**}. All research proposals must be submitted in English language only.

Application can be submitted to the office of the Member Secretary, IEC IGMC Shimla on any working day.

All the proposals and documents must be submitted at least three weeks in advance from the scheduled date of IEC meeting.

Ten copies of study proposals (with all the documents Form II, Form IVA & IVB, Form V) must be submitted for full review of the Ethics Committee along with application form duly signed and dated by the investigator(s). A soft copy of the proposal must also be submitted on the email id of IEC.

Conduct ofClinical Trial

Clinical trial should beconductedin accordance with theprinciples as specified in ThirdSchedule of New Drugs and Clinical Trials Rule 2019, principles of Good Clinical Practice and ICMR National Ethical guidelines for biomedical and health research involving human participants.2017.

Allclinicaltrialsmustbeconductedinamannerthatensuresthedignity,rights,safetyand wellbeing of the study participants.

Writteninformedconsentmustbeobtainedfromeachparticipant.beforeanyresearchrelated procedure is performed.

TheIECwillreviewthenoofpatientsrecruitedforthetrialasperguidelines,droppedoutand reasons for drop out of study participants.

Adherencetotheclinicaltrialprotocolisessentialandifamendmentoftheprotocolbecomes necessary the rationale for the amendment shall be provided in the form of a protocol amendment.

Protocol amendments, if become necessary before initiation or during the course of a clinical trial, all such amendments should be submitted to the Central Licensing Authority in writing along with the approval by the Institutional Ethics committee IGMC Shimla.

4.5.7.No deviations from or changes to the protocol should be implemented without prior written approval of the ethics committee and Central Licensing Authority except when it is necessary to eliminateimmediatehazardstothetrialsubjectorwhenchangeinvolvesonlylogisticoradministrative or minor aspects of the trial. All such exceptions must be immediately notified to the ethics committee as well as to the Central Licensing Authority.
Administrativeorlogisticchangesorminoramendmentsintheprotocolshouldbenotifiedtothe Central Licensing Authority within thirty days.

AllthePIundertakingclinicaltrialsaretodoCTRIregistrationmandatorily andCTRIreg.no. should be communicated to the committee.

Incaseaclinicaltrialistobeconductedincollaborationwithaninternationalagency,itis mandatory to register the trial with the Health Ministry's Screening
Committee.(https://www.icmr.nic.in/content/guidelines.
In case the PI is collaborating with other institutions for clinical trial, Memorandum of Understanding(MOU)forcollaborativestudies/Agreementbetweencollaboratingpartnersisto be submitted.
EthicsCommitteeclearanceofNodal/othercentersincaseofmulticentricstudies(ifapplicable) is also to be submitted.

Informed Consent–

In all trials, a freely given, informed, written consent is required to be obtained from each study subject. The Investigator must provide information about the study verbally as well as using a patient information sheet, in a language that is nontechnical and understandable by the study subject.
The subject's consent must be obtained in writing using an "Informed Consent Form". Both the patient information sheet as well as the informed consent form should have been approved by the ethics committee and furnished to the Central Licensing Authority. Any changes in the informed consent documents should be approved by the ethics committee and submitted to the Central LicensingAuthority before such changes are implemented.
Where a subject is not able to give informed consent (e.g. an unconscious person or a minor or those suffering from severe mental illness or disability), the same may be obtained from a legally acceptable representative (LAR). A legally acceptable representative is a person who is able to give consent for or authorize an intervention in the patient as provided by the law of India.
If the trial subject/ his or her legally acceptable representative is unable to read or write, an impartial witness should be present during the entire informed consent process who must append his or her signature to the consent form.
In case of clinical trials on pediatrics, the subjects are legally unable to provide written informed consent, and are dependent on their parent or legal guardian to assume responsibility for their participation in clinical studies. In such case-
a.Writteninformedconsentshouldbeobtainedfromtheparentorlegalguardian.However,all pediatric participants should be informed to the fullest extent possible about the study in a language and in terms that they are able to understand.
b.Where appropriate, pediatrics participants should additionally assent to enroll in the study. In case of matureminors(7-12years)oralconsentshouldberecordedandadolescents(12-18years)should personallysignanddateaseparatelydesignedwrittenassentformwhichalsoistobesignedbythe parents or LAR.
c. Although a participant's wish to withdraw from a study must be respected, there may be circumstances in therapeutic studies for serious or life-threatening diseases in which, in the opinion of the Investigator and parent or legal guardian, the welfare of a pediatrics patient would be jeopardized by his or her failing to participate in the study. In this situation, continued parental or legal guardianconsent should be sufficient to allow participation in the study.

A checklist of essential elements to be included in the study subject's **informed consent document as well as a format for the informed consent form for trial subject** is given (**Form IV A & IV B**).
Anaudio-videorecordingoftheinformed consentprocessincaseof vulnerablesubjectsin clinical trials of New Chemical Entity or New Molecular Entity including procedureof providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record:

Provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record.

Reviewofon-going studies

The Institutional Ethics committee IGMC Shimla will make, at appropriate intervals, an ongoing review of the trials as per approved protocol. A sub-committee will be formed for the review of ongoing clinical trials and such a review may be based on the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or visiting the study sites as per requirement of the ongoing study.

The continuing review of protocols is to be done by the ethics committee once in six months for the clinical trials, and once in a year for the academic studies.

A decision regarding whether the project needs to be reviewed more frequently will be taken during the IEC meeting in which the project is finally approved and will be recorded in the minutes. A fresh decision to increase review may be taken if required based on the SAE reports, monitoring reports, or safety concerns. The IEC will review the progress made in the protocol (number of patients recruited, dropped out, reasons for drop-out), the occurrence of unexpected events or problems, and compliance of the investigator regarding IEC communication.

If the PI fails to submit documents for continuing review within the stipulated date, the Member Secretary will send a reminder notice asking the PI to submit the documents within 7 days. Further, non-response or failure to submit documents will be discussed in the full board meeting oftheIEC.Action could beoneofthefollowing: onemorereminderand askingthePItogivean explanation for the failure to submit documents / withdrawing the ethical approval granted and asking the PI not to continue the study/ any other action which is deemed appropriate. The head of the institution will be informed of the decision of the IEC.

Procedureforattendingtheissuesrelatedtoprotocoldeviation/non-compliance/violations

The Secretariat will notify the Member Secretary of any protocol deviation/violation report received from the PI/ from any source within 2 working days of receipt of the notification.

Theactionofthe IECwill bebased on:

The nature and seriousness of the deviation / violation, Frequency of deviation/ violation in the study in the past, Frequency of deviation/ violation in previous studies conducted by the same PI/ Co-PIor in the same department.

Member Secretary will decide on the impact of the protocol deviation / violation and act accordingly. Depending upon the seriousness, the ethics committee shall do the following:

- AskPIforwritten clarificationas soonas thedeviation is received

- Iftheimpactisserious,thisreportwillbesharedwiththeChairpersonandtwoormoreethics committee members may be designated by the Chairperson for investigating the issue.

4.8.3 The Secretariat will put up the information and communication at the next full committee meeting for discussion. The Chairperson will take a final decision depending on the seriousness of the violation. Thedecision will be taken to ensure that the safety and rights of the research participants are safeguarded. The decision will be taken by consensus, and the quorum required for the meeting issameasthatrequiredfortheinitialapprovaloftheprotocol.TheDCGI/otherrelevantregulatory authorities will be informed.

Serious adverse events Review/ Reporting and recommendation for payments of compensation as per chapter VI of New Drugs and Clinical Trials Rules 2019

Any serious adverse events should be notified to the IEC IGMC Shimla within 24 hours by the PI. Serious adverse events during clinical trial shall be reported in accordance with the New Drugs and Clinical Trials Rules, 2019. Any report of the serious adverse event, after due analysis shall be forwarded by the sponsor to the Central Licensing Authority, the Chairperson of the ethics committee and the head of the institution where the trial has been conducted, within fourteen days of knowledge of occurrence of the serious adverse event as specified in Schedule3 of New Drugs and Clinical Trials Rules, 2019.

The IEC Secretariat will receive the following documents within the specified time frame if an SAE is experienced by any research participant (**Form VI**):

- InitialSAEreporttobesubmittedbythe PrincipalInvestigator(PI)within24hoursof occurrence.
- Dueanalysis should besubmitted by thePIwithin 14days from theoccurrenceof theSAE
- Dueanalysis willalso besubmittedby thesponsorwithin 14 days
- Thefollow up reportsofall on-siteSAEtill theevent is resolved.

TheIECSecretariat willverify thatthereportiscompleteinall respectsandthat ithasbeen receivedat the IEC office within the specified timelines. If the report has been received beyond the specified time, itwill be considered as a protocol violation and action should be taken as described in SOP for protocol deviations. The IEC Secretariat will sign and write the date on which the report is received. The Secretariat will forward these reports to the SAE Subcommittee.

The SAE subcommittee will review the reports/ case history with a special focus on relatedness to the clinical trial, medical management and financial compensation to be given to the research participants. The applicable formulae and guidelines from the regulatory authority will be used during this discussion. The SAE subcommittee will hold the meeting with investigators and site visits as required. If deemed necessary, the SAE subcommittee may refer the issue to the IEC full board. The report of SAE subcommittee will be presented in the IEC full board meeting. An emergency meeting of IEC may be held for this purpose.

The PI will be requested to reply to the query letter on the SAE report within 7 working days. The ethics committee shall forward its report or order on the event, after due analysis, along with its opinion on the financial compensation, if any, to be paid by the sponsor or his representative or institution or Centre, as the case may be, in accordance with Chapter VI of New Drugs and Clinical Trials Rules, 2019.

The opinion regarding relatedness, medical management and compensation for research related injury will be communicated by the Ethics Committee to the Licensing authority (DCGI) within 30 calendar daysof the occurrence of the SAE in case of regulatory clinical trials.

* All SAE's following clinical/ drug trial are to be reported by the principal investigator through SUGAM portal within 24 hrs of occurrence.

SOP.9.

PROCEDURESFORREVIEWANDON-SITEMONITORINGOFAPPROVED/ONGOING CLINICAL TRIALS.

1. PURPOSE

Todescribetheprocess ofreviewandon-sitemonitoringofprotocolsapproved.

2. SCOPE

ThisSOPisapplicabletotheregulatorytrialsandinterventionstudiesforwhichon-sitemonitoringis undertaken by the Ethics Committee

3. RESPONSIBILITY

AllmembersofEthicsSub-Committeeareresponsibleforimplementingthis SOP.

4. PROCEDURE

Reviewofon-goingstudies

The Institutional Ethics committee IGMC Shimla will make, at appropriate intervals, an ongoing review of thetrials as per approvedprotocol. A sub-committee will be formed for the review of ongoing clinical trials and such a review may be based on the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or visiting the study sites as per requirement of the ongoing study.

Thecontinuingreviewofprotocolsisdonebytheethicscommitteeonceinsixmonthsfortheclinical trials, and once in a year for the academic studies.

The decision regarding whether the project needs to bereviewed more frequently will be taken during the IEC meeting in which the project is finally approved and will be recorded in the minutes. A freshdecision to increase review may be taken if required based on the SAE reports, monitoring reports, or safety concerns.

The IEC will review the progress made in the protocol (number of patients recruited, dropped out, reasons for drop-out), the occurrence of unexpected events or problems, and compliance of the investigator regarding IEC communication.

4.1.4 If the PI fails to submit documents for continuing review within the stipulated date, the Member Secretary will send a reminder notice asking the PI to submit the documents within 7 days. Further, non-response or failure to submit documents will be discussed in the full board meeting of the IEC. Action could beoneofthefollowing:onemorereminderandaskingthePItogiveanexplanationfor thefailuretosubmit

documents / withdrawing the ethical approval granted and asking the PI not to continue the study/ any other action which is deemed appropriate. The head of the institution will be informed of the decision of the IEC.

OnSite monitoring

Time and Site of Visit: The decision letter issued to the PI during approval of the protocol will havethe statement on on-site monitoring of the study.
Theroutine monitoring oftheprotocols will be doneatleast oncein a year.

Twominimumvisitsaredoneforastudyfrominitiationtillcompletion. Visit -

1:During the progress of the study.
AfterthePIsubmitsthe firstprogress report(sixmonths afterinitiation ofthe study);Verification of writtenrecords
Visit-2:Annuallytillthecompletionofthe study.
"For-cause monitoring" will be performed at sites for reasons identified by any member of the IEC, after approval by the Chairperson. The reasons for identifying a particular site for "for-cause monitoring" could include any one or more of the following:
Large number of Serious Adverse Events (SAE) reports/ Scientific misconduct/ Large number of Protocol deviations/ Complaints received from subjects, head of the institution or any other person (anonymous complaints received shall be entertained if they affect subject safety

During the Visit:

TheMonitoringteam willfollowthechecklist and:

1. Checkthelog ofdelegation ofresponsibilities ofstudy team
2. CheckifthesiteisusinglatestIECapprovedcurrentversionsoftheprotocol,informedconsent documents, case record forms, diaries, advertisements, etc.
3. Observetheinformedconsentprocess,ifpossible
4. Reviewrandomlyselectedparticipants filestoensurethatparticipants aresigningthecorrectinformed consent,
5. Check investigational product accountability is adequately controlled and documented throughout the product flow at the study site (arrival, dispensing, use, return from the subject and return/destruction after the study),
6. Check for storage times, conditions and expiry dates to be acceptable and sufficient supplies available, wherever applicable,
7. Verifythattheinvestigatorfollowstheapprovedprotocolandallapprovedamendment(s),ifany,
8. Ensurethatthe investigatorand theinvestigator'strial staffareadequatelyinformed aboutthetrial,
9. Verify that the investigator and the investigator's trial staff are performing the specified study functions,inaccordancewiththeapprovedprotocolandanyotherwrittenagreementbetweenthe

sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals,

10. Verifythat theinvestigator isenrolling onlyeligible subjects,
11. DeterminewhetherallSAEsareappropriatelyreportedwithinthetimeaspertheapplicableregulatory requirement(s). Case record forms would be checked to review the safety data i.e. Adverse Events (AEs) and SAEs for the volume or severity of adverse events,
12. Reviewthe projectfilesof thestudy toensurethat documentationis filed appropriately.
13. Reviewthe sourcedocuments fortheircompleteness,
14. Collectviewsofthe studyparticipants,if possible.

4.3. Decision taken by the Sub-Committee will be brought to the notice of the main committee members atnext regular meeting of the IEC and their concurrence taken into record.

SOP.10.

POLICYFORFINANCIAL DECLARATIONOFPAYMENTSOFETHICS COMMITTEE.

1. PURPOSE

ThisSOPdescribesthe**financialtransparency**inInstitutionalEthicsCommitteeIGMCShimla.

2. SCOPE

This SOP is applicable to financial transactions of the ethics committee including payments received and disbursed by the Ethics Committee IGMC Shimla

3. RESPONSIBILITY

TheMemberSecretary,theSecretariatandallmembersofIECareresponsibleforimplementingthis SOP.

4. PROCEDURE

Everyresearch proposalwill havetopay afeeas under

a. Fordrug trials asum of Rs.10,000 /-(Ten thousand only) per project.
b. Forhuman studiesother thandrug trialsasum ofRs. 5000/-(Five thousand only).

Thefeeistobepaidintheformofademanddraftpayabletо MemberSecretaryInstitutionalEthics Committee, IGMC Shimla. The Ethics Committee has an account for the same.

TherewillhoweverbenofeesforthethesisprotocolsofMD/MS,DM/MCHandprojectsofMBBS student of this institution.

The external members of the Institutional Ethics Committee IGMC Shimla receive honorarium for the review work and the meetings attended. The remuneration is rupees 1,000/ meeting which is paid through the cheque from the account of the Ethics Committee.

Forthe expenditures ofrefreshmentsservedin themeetings,remittance isdonethroughthisaccount. For the day to day expenditures of stationery, transport and other miscellaneous expenditures payment is made through the ethics committee account.

This account is audited annually and utilization of the amount is monitored.

SOP.11.

PROCEDUREFORDECISIONREGARDINGAPPROVALOFSUBMITTEDRESEARCH PROPOSALS.

1. PURPOSE

Tomakea**decisionregardingapprovalofthesubmittedresearchproposal**.

2. SCOPE

Applicabletothe IECof IGMCShimla

3. RESPONSIBILITY

All **membersof IEC**areresponsible forimplementingthis SOP.

4. PROCEDURE

In making decision on application for the ethical review of any research proposal, IEC will consider the following:

Member having a **conflict of interest** will indicate to the Chairman prior to the review of application and same will be recorded in the minutes.

Where there is conflict of interest, that Member will be withdraw from the decision-making procedure.

Adecisionwillonlybe takenwhensufficient timehasbeenallowedforthe review.

Decision will only be taken at meeting **where a quorum** (e.g. Five in a Committee of 10) is complete after ensuring that quorum is **as per ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Subjects 2017, New Drugs and Clinical Trials Rules 2019 and GCP Guidelines**.

Decision will be taken only after reviewing a complete application with all the required documents necessary for proposal.

Only IEC 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.

SOP.12.
PROCEDUREFORNOTIFYING REVIEWOUTCOME OFSUBMITTED PROPOSALS

1. PURPOSE

To**communicatethedecision**ofIECtothe applicant.

2. SCOPE

Applicabletothe IECof IGMCShimla

3. RESPONSIBILITY

MemberSecretary isresponsibleforimplementingthis SOP.

4. PROCEDURE

A decision of the IEC will be communicated to the applicant. A certificate of the approval will be sent to the applicant within 2 weeks (**Document-3**). All the approvals will be valid only for 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.

Thecommunicationofthedecisionwill include:

- Nameand addressof IEC.

- Thedate and placeof decision.

- Thename and designation of the applicant.

- Titleof theresearch proposal reviewed

- Theclearidentificationofprotocolno., versionno.,date,amendmentno. date.

- Aclear statementof decision reached.

- AnyadvicebytheIECto theapplicant.

- In case of conditional decision any requirement by IEC including suggestions for revision and the procedure for having the application reviewed.

- Incaseofrejectionofthe proposal,reason(s)fortherejectionwillbeclearly stated.

- Signatureofthemember secretarywithdate.

SOP.13.

PROCEDUREFORFOLLOWUPOFONGOINGRESEARCHPROPOSALSBY THE INSTITUTIONAL ETHICS COMMITTEE

1. PURPOSE

Tocarryoutthe**follow-up** oftheresearchproposals.

2. SCOPE

Applicabletothe IECof IGMCShimla

3. RESPONSIBILITY

Allmembersof IECandthe investigatorsareresponsible forimplementingthis SOP.

4. PROCEDURE

IEC 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 research.

Progressofalltheresearchproposalswillbefollowed **at regular interval**ofonceayear.Butin special situations, IEC will conduct the follow up **review at shorter intervals** basing on the need, nature and events of research project.

All the requirements and procedures for the follow-up review will be similar to that of initialand main review.

Followinginstancesandeventswillrequirethefollow-upreview:

Anyprotocolamendment likely to affectrights, safety orwellbeing of research subject of conduct of study.

Serious or unexpected ADRrelatedtostudyorproduct,actiontakenbyInvestigator,sponsor and Regulatory authority.

Anyevent/informationthat**mayaffectthe benefit/riskratioofthe study**.

A**decisionoffollowupreview**willbeissuedandcommunicatedtotheapplicantindicating **modification/suspension/termination**oftheproject.

Incaseof**prematuresuspension/termination**,the**applicant**mustnotifytheIECofthe reasons for the suspension/termination with a summary of the result.

Applicant must inform the time of completion of study and must send the result summary to IEC **annually or earlier** if required by IEC. IEC must receive a copy of **final summary of study completed** from the applicant.

SOP.14

PROCEDURES TO ARCHIVE THE STUDY RELATED DOCUMENTS, PROCEEDINGS AND COMMUNICATIONS

1. PURPOSE

Toarchive thestudy relateddocuments, proceedingsand communications.

2. SCOPE

ApplicabletotheOffice of IECofIGMCShimla

3. RESPONSIBILITY

TheMemberSecretaryandSecretariatisresponsibleforimplementingthis SOP.

4. PROCEDURE

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

Only persons, who areauthorized by the chairman of IEC will havetheaccess to thevarious documents.

All the document related to research proposals will be archived for a minimum period of 5 years in the institute, following the completion/termination of the study.

Nodocuments(exceptagenda)willbe retainedbyanyIECmember.

At the end of each meeting, every member must return all the research proposals and the documents to IEC office staff. They will archive one copy in IEC office and other copies will be destroyed after one year.

Followingdocumentswillbefiledandarchivedwithproperlabelonthetopoffilefor easy identification of proposal.

Theconstitution,writtenSOPsof theIEC,andregular(annual) reports.

4.6.2ThecurriculumvitaeofallIECmembers.

Arecordofallincomeandexpensesifany,oftheIEC,includingallowancesand reimbursements made to the secretariat and IEC members.

Thepublished guidelinefor submission establishedby the IEC.

4.6.5Theagendaof theIEC meetings. Theminutes oftheIEC meetings.

Onecopyof allthe materialsubmittedbyan applicant.

Acopy ofthedecision & anyadviceor requirementssent to an applicant.

4.6.8Allwrittendocumentationreceivedduringthe follow-up.

4.6.9.Thenotificationof completion,prematureterminationofstudy.

4.6.10Thefinalsummary orfinal reportofthe study.

InstitutionalEthicsCommittee(HumanStudies) Indira Gandhi Medical College, Shimla

GENERALGUIDELINES

1. **Meeting dates:** The meeting of Institute Ethics Committee will be held in the first week of the months of April, August and December.

2. **Project Submission Deadline**: 5th day of March/ 5th day of July/ 5th day of November. Applications received after the deadline will be taken up in the next meeting.

3. All proposals should be submitted in the prescribed application form (Form IA/IB/II/IV/V whichever applicable) as mentioned in the Standard Operating Procedures(SOPs) available on the website.

4. All relevant documents and the required number of copies should be enclosed with application form.

5. A total of 10 hard copies should be submitted to the IEC Secretariat and one soft copy in pdf format to be mailed to **email id-iec.igmc.sml@gmail.com**from the email of the Principal Investigator of the project **or email of the postgraduate student/ Guide (for MD/MS/DM/MCH/PhD thesis protocols) or guide in case of (MBBS student projects)**. The proposal should be complete in all aspects.

6. For research projects involving clinical drug trials, the project also needs to be registered withthe Clinical Trial Registry in ICMR (CTRI). For details visit Website: **www.ctri.nic.in**

7. In case a clinical trial is to be conducted in collaboration with an international agency, it is mandatory to register the trial with the Health Ministry's Screening Committee.(https://www.icmr.nic.in/content/guidelines)

8. Thedateofmeetingwillbeintimatedtotheresearcher,tobepresent,ifnecessary,tooffer clarifications or will be called during the meeting, if needed.

9. TheIECwillreviewevery researchproposalonhumanparticipantsbeforetheresearchisinitiated.

10. After the research is initiated it is compulsory for the Principal Investigator to submit the annual progress report of the research (or earlier if desired by the IEC).

11. Finalreport shouldbe submitted attheendofthestudy.

12. Forresubmittedproposals, 3hardcopiesalongwithsoftcopyonemailof the InstitutionalEthics Committee (from the email of the Principal Investigator of the project) should be submitted. Point wise reply to IEC letter of comments to be given in the covering letter.
13. Prematuretermination/suspension/discontinuationofthestudyistobeinformedtothe Institutional Ethics Committee (human Studies) IGMC, Shimla.
14. Any Severe Adverse Effect (SAE) or any unexpected adverse event should be reported to the Institutional Ethics Committee within 24 hours. The report of any SAE or unexpected adverse event after analysis must be submitted to the Chairman IEC and the Head of Institution where trial is being conducted within 14 calendar days of SAE.
15. The requisite application fee wherever applicable to be submitted at the time of application or before the letter of permission by IEC.
16. For further details refer to the Standard Operating Procedures (SOP) provided on the IGMC website.
17. Applicantsarealso requested toconsult followingdocumentsbeforesubmissionofthe proposal.

- the ICMR National Ethical Guidelines on Biomedical Research involving Human participants 2017(https://icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf),
- New Drugs and Clinical Trials Rules 2019 https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf
- GuidelinesforGoodClinicalPractice-ICH (https://www.ich.org/fileadmin/Public_Web_Site/ICH...../E6/E6_R1_Guideline.pdf)

Important information

Thedocumentsshouldbesubmittedto:Sh.NityaNandSharmaSuptd.SrGradeII,Academic Section, Principal Office, Indira Gandhi Medical College Shimla

Acompletesetofdocumentsshouldalsobeemailedtoiec.igmc.sml@gmail.comIncomplete applications will be returned.

Directorate of Medical Education & Research
Himachal Pradesh, Shimla -171009.

4073
22/12/22

OFFICE ORDER

No. HFW (DME)-F(8)-1/2019-Vol-II- Dated: Shimla-9, the /12/ 2022.

In exercise of powers delegated to me vide para No 3.5 of the notification No.HFW-B(G)1-2/2017 dated 22.02.2019 issued by the Govt. of Himachal Pradesh, Department of Health & Family Welfare under "Research Grant Programme", the Ethical Committee comprising following members is reconstituted in respect of IGMC Shimla for ensuring smooth functioning/ developmental activities in the institution:

Sr.No.	Name	Designation
1.	Dr. R. K. Kaushal, Clinical, Ex-Professor and HOD Pediatrics Deaprtment, IGMC Shimla.	Chairman.
2.	Dr. Anita Thakur (Designated) Professor, Deptt. of Community Medicine , IGMC Shimla.	Member Secretary
3.	Sh. Sarabjeet Singh Bobby, R/o 150 Lower Bazar Shimla.	Member (Layperson)
4.	Mrs. Kalpna Sanghaik, Social Worker, Deptt. of Radiotherapy, IGMC Shimla.	Member (NGO)
5.	Sh. Shashi Kumar Shishoo, Lawyer, HP High Court Shimla.	Member (Lawyer)
6.	Dr.(Mrs) Sanju Karol, Professor Department of Economics, Himachal Pradesh University Shimla.	Member (Social Sciences)
7.	Dr. P.K. Kaundal, Professor, Department of Pharmacology, IGMC Shimla.	Member (Basic Sciences)
8.	Dr. Puneet Mahajan, Associate Professor, Department of Surgery, IGMC Shimla.	Member (Clinical)
9.	Dr. Parmod Kumar Jaret, Associate Professor, Department of Medicine, IGMC Shimla.	Member (Clinical)
10.	Dr. Anmol Gupta, Professor, Department of Community Medicine IGMC Shimla.	Member (Epidemiologist)

The main functions of the committee will be as under:

(i) Research related activities which involve human aspects.
(ii) Through examination of projects.
(iii) Functioning and Teaching of UGs/PGs Students in the Institution.
(iv) Better Hospital Services.

Sd/-
Director
Medical Education & Research,
Himachal Pradesh, Shimla-9.

DIRE. MEDICAL EDUCTION & RESE
DESPATCH
20 DEC 2022
H.P. SHIMLA-171009

Endst No: As above. 11992 Dated: Shimla-9, the /12/2022.

Copy forwarded to the Principal IGMC Shimla w.r.t. letter No. HFW-(MC-II) B(12) Ethics/2020-27485 dated 07.11.2022 for favour of information and necessary action please.

Dy. II
Principal 22.12.22
Addl.
A.C.

Sh. Suraj Ram
22/12/2022

Director 22/12
Medical Education & Research,
Himachal Pradesh, Shimla-9.

INDIRA GANDHI MEDICAL COLLEGE, SHIMLA-171001
No. HFW(IGMC)B(12)Ethics/2022-30805 Dated: 23-12-22
Copy forwarded to Dr. Anita Thakur, Professor (Designated) Community Medicine through Professor & Head, Deptt. of Community Medicine, IGMC, Shimla for information and further necessary action.

Vegist

Annexure1 Document-1

LetterRef:No:

From Date:

Principal

IGMCShimla

To

Subject: **ConstitutionofInstitutionEthicsCommittee(Humanstudies)**

DearSir/Madam

On behalf of Indira Gandhi Medical College Shimla, I request your concurrence for induction as a Member/Member Secretary/Chairman of Institutional Ethics Committee of this institute. Kindly send your written acceptance in the enclosed format and provide the necessary information requested.

Onreceiptof youracceptance, thenamewill besent properordersfrom Govt.of H.P.

YourSincerely,

Signature:

Name:

ANNEXURE.2: **Document-2**

From

……

……

To

Principal,
IGMC,Shimla

Subject: Consent to be a Member /Member Secretary /Chairman of Institutional Ethics Committee (Human studies)

DearSir/Madam

In response to your letter stated above, I give my consent to become a member/member secretary /chairman of IEC of IGMC Shimla. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues. I shall be willing for my name, profession and affiliation to be published I shall not keep any literature or study related document with me after the discussion and final review.

Ishallmaintainalltheresearchprojectrelatedinformationconfidentialandshallnotrevealthesame to anyone other than project related personnel.
IherewithenclosemyC.V.

Thanking you,

Your Sincerely,

Signature…….

Nameofthe Member .....Date:

Address:Telephone

No:Off: Res:

Email:

ANNEXURE.3: **Document:3**

Formatforaccordingapproval totheclinicaltrialprotocolsbytheEthics Committee

To

Dr.

DearDr._____

The Institutional Ethics Committee reviewed and discussed your application to conduct theclinical trial entitled "……" on..... date

Thefollowing documents were reviewed:

a. Trial protocol (including protocolamendments), date _____versionno_____

b. Patient Information Sheet and Informed Consent Form (including updated if any) in English and/or vernacular language.

c. Investigator's Brochure, dated _____version no._____

d. Proposedmethodsforthepatientaccrualincludingadvertisement(s)etc.proposedtobeused for the purpose.

e. PrincipalInvestigator'scurrentCV.

f. InsurancePolicy/Compensationforparticipationandforseriousadverseeventsoccurring during the study participation.

g. Investigator'sAgreementwiththe Sponsor.

h. Investigator'sUndertaking
Thefollowingmembersoftheethicscommitteewerepresentatthemeetingheldon(date,time, place)

_____ChairmanoftheEthics Committee

_____Membersecretary of theEthics Committee

_____Nameofeachmemberwith designation

1. Approvedinitspresentform2.Revisionwithminormodificationsandapprovalafterre-examinationbymembersecretaryorexpeditedreviewsub-committee.3Revisionwithmajor

modifications for resubmission- to be placed before full IEC for reconsideration. 4 Not approved- with clear reasons for non- approval.

The approval is subject to quarterly/ half yearly/annual review of the study. The Institutional Ethics Committee is to be informed about any serious adverse events occurring in the course of the study, any changes in the protocol and patient information sheet/informed consent form and is to be provided a copy of the final report on completion of the study.

Yours sincerely

MemberSecretary,EthicsCommittee.

ANNEXURE.4: **FormIA**

Proforma to be submitted to the Institutional Ethics Committee (Human studies) (for projects other than those mentioned in form IB**)**

Kindlysubmit 10copiesof proformaand consent forms in English & Hindi to theMember Secretary, Institutional Ethics Committee (Human Studies), IGMC Shimla

1. Titleof the project:
2. Nameoftheinvestigators/co-investigators withdesignation&department:
3. Numberofprojects already with theinvestigators/co-investigators:
4. DateofapprovalbyscientificcommitteeIGMC Shimla
5. Sourcesoffunding
6. Objectivesofthestudy:
7. Justificationfor theconduct ofthestudy:
8. Methodology:Itshouldprovidedetailsofthenumberofpatients,inclusioncriteria,exclusion criteria, control(s), study design, dosages of drug, duration of treatment, investigations to be done etc.:
9. PermissionfromDrugControllerGeneralofIndia(DCGI)ifapplicable
10. Costsinvolved(Appx.InRs)

    a) Investigations b) Disposables

    c) Exempted d)Drugs/Contrast Media

11. Ethicalissuesinvolved inthestudy:

    lessthanminimalrisk/morethanminimalrisktothestudysubjects(forguidancepleaseconsult ICMR guidelines.

12. Do you need exemption from obtaining Informed Consent from study subjects- if so, give justifications?
13. WhetherConsentformspart1 and2in Englishandin locallanguage are enclosed?

14. Documents attached

(a) BriefCVofinvestigators(includingno.ofprojectswithhim/her)-Neededonlyforinvestigator/s from outside IGMC Shimla Brochure

(b) Investigator'sBrochure

(c) Others

15. Conflictof interestforanyotherinvestigator(s)(ifyes,pleaseexplainin brief)

16. 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 requirement of the ICMR guidelines (2017)

    Signatureof the Investigators:

    Signatureof theHeadofthe 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 investigators must provide information to the subjects in a simple language, and it should address the subjects, in a dialogue format)

ANNEXURE.5: **FormIB**

ProformatobesubmittedtotheEthicsCommittee(Humanstudies)(forMD/MS/DM/MCH /PhD(forThesisorDissertation/MBBSstudentprojects)

Kindly submit 3 copies of proforma and consent forms in English & Hindi to the member Secretary, Institute Ethics Committee (Human Studies), IGMC Shimla

1. Titleof the project:
2. NameandDepartment/addressoftheinvestigators:
3. NumberofFaculty (Guide/Co-guide)with designation&department:
4. Dateof approvalby InstituteResearchCouncil/ScientificAdvisory/Thesisprotocolscrutiny committee.
5. Sourcesoffunding
6. Objectivesofthestudy:
7. Justificationfor theconduct ofthestudy:
8. Methodology: It should provide details of number of patients, inclusion criteria, exclusion criteria, control(s), study design, dosages of drug duration of treatment, investigations to be done etc:
9. PermissionfromDrugControllerGeneralof India(DCGI)ifapplicable
10. Ethicalissuesinvolved inthestudy:

Norisk/lessthanminimalrisk/morethanminimalrisktothestudysubjects(forguidanceplease consult ICMR guidelines2017).

11. Do you need exemption from obtaining Informed Consent from study subjects- if so give justifications?

12. WhetherConsentforms part 1 and2 inEnglishandinlocal language are enclosed?

13. Conflictofinterestforanyotherinvestigator(s)(ifyes,please explainin 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 requirement of the ICMR guidelines (2017)

Signatureof the Investigators:

Signatureof theHeadoftheDepartment

(**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 investigators must provide information to the subjectsinasimplelanguage,anditshouldaddressthesubjects,inadialogueformat

ANNEXURE.6: FormII

CONTENTSOFTHEPROPOSEDPROTOCOLFORCONDUCTINGCLINICALTRIALS

1. TitlePage

a. Fulltitleoftheclinicalstudy.

b. Protocol/Studynumber,andprotocol versionnumberwith date

c. TheINDname/numberof theinvestigational drug

d. Competenameand addressof theSponsorand contractresearch organizationif any

e. ListoftheInvestigatorswhoareconductingthestudy,theirrespectiveinstitutional affiliations and site locations

f. Name(s)ofclinicallaboratoriesandotherdepartmentsand/orfacilitiesparticipatinginthestudy.

2. Table of Contents

AcompleteTable ofContents includingalist ofallAppendices.

1. Backgroundand Introduction

a. Preclinicalexperience

b. Clinical experience

Previous clinical work with the new drug should be reviewed here and a description of how the current protocol extends existing date should be provided. If this is an entirely new indication, how this drug was considered for this should be discussed. Relevant information regarding pharmacological, toxicological and other biological properties of the drug/biologic/medical device, and previous efficacy and safety experience should be described.

2. Study Rationale

This section should describe a brief summary of the background information relevant to the study design and protocol methodology. The reason for performing this study inthe particular included by the protocol should be provided.

3. AStudy Objective(s)(primaryas wellas secondary)and theirlogical relationsto thestudy design.

4. Study Design

OverviewofthestudyDesign: Includingadescriptionofthetypestudy(i.e.double-blind, multi centre, placebo controlled,etc.),adetail ofthespecifictreatment groups and numberof study Subject in each group and investigative site, Subject number assignment, and the type, sequence and duration of study periods.

I. Flowchart ofthe study

II. Abriefdescriptionofthe methodsandproceduresto beusedduringthestudy.

III. DiscussionofStudydesign: Thisdiscussiondetailstherationaleforthedesignchosenfor this study.

5. Study Population: the number of Subjects required to be enrolled in the study at the Investigative site and by all sites along with a brief description of the nature of the Subject population required is also mentioned.

6. Subject Eligibility

a. InclusionCriteria

b. Exclusion Criteria

7. StudyAssessments –planproceduresand methodstobedescribedin detail

8. Study Conduct stating the types of study activities that would be included in this section would be: medical history, type of physical examination, blood or urine testing electrocardiogram (ECG), diagnostic testing such as pulmonary function tests, symptom measurement, dispensation and retrieval of medication, Subject cohort assignment, adverse event review etc.

   EachvisitshouldbedescribedseparatelyasvisitI, Visit2,etc.

   Discontinued Subjects: Describes the circumstances for subject withdrawal, dropouts, or other reasons for discontinuation of subjects. State how drop outs would be managed if they would be replaced

   Describe the method of handling of protocol waivers, if any. The person(s) who approves all such waivers should be identified and the criteria used for specific waivers should be provided.

   Describe how protocol violations will be treated, including conditions where the study will be terminated for non-compliance with the protocol.

9. Study treatment

a. Dosingschedule(dose, frequency, anddurationof theexperimentaltreatment)Describe

   the administration of placebos and/or dummy medications if they are part of the treatment plan. If applicable, concomitant drugs(s), their doses, frequency and duration of concomitant should be stated.

b. Study drug supplies and administration: A statement about who is going to provide the study medication and that the investigational drug formulation has been manufactured following all regulations, details of the product stability, storage requirement and dispensing requirement should be provided.

c. Dose modification for study drug toxicity: rules for changing the dose or stopping the study drug should be provided

d. Possibledruginteractions

e. Concomitant therapy: the drugs that are permitted during the study and conditions under whichtheymaybeusedaredetailedhere.Describethedrugsthatasubjectisnotallowed to use during parts of or the entire study. If any washout period for prohibited medication are needed prior to enrolment, these should be described here.

f. Blinding procedures: A detailed description of the blinding procedure if the study employs a blind on the investigator and / or the subject

g.Unblindingprocedures:Ifthestudyisblinded,thecircumstancesinwhichunblindingmay be done and the mechanism to be used for unblinding should be given

10. AdverseEventsDescription ofexpected adverseevents shouldbe given.

11. EthicalConsiderations:GivetheSummaryof:

    a. Risk/benefit assessment:

    b. EthicsCommitteereviewandcommunications

    c. Informedconsent process

    d. Statementofsubjectconfidentiallyincludingownershipofdatecodingprocedures

12. Study Monitoring and Supervision: a description of study monitoring policies and procedures should be provided along with the proposed frequency of site monitoring visits, and who is expected to perform monitoring

    Case Record (CRF) completion requirements, including who gets which copies of the forms and any specifics required in filling out the forms CRF corrections requirements, including who is authorized to make corrections on the CRF and how queries about study data are handled and how errors, if any, are to be corrected should be stated.

    Investigator study files, including what needs to be stored following study completion should be described.

13. InvestigationalProductManagement

    a. Give Investigational product description and packaging (stating all ingredients and the formulations of the investigational drug and any placebos used in the study)

    b. Theprecisedosing requiredduringthestudy

    c. Method of assigning treatments to subjects and the Subject identification code numbering system

    d. Method of assigning treatments to subjects and the subject identification code numbering system

    e. Storageconditionsforstudy substances

    f. Investigational product accountability: Describe instructions for the receipt, storage, dispensation,andreturnoftheinvestigationalproductstoensureacompleteaccountingofall investigational products received, dispensed, and returned /destroyed.

    g. Describepolicyandprocedureforhandlingunusedinvestigationalproducts.

14. Data Analysis:

    Provide details of the statistical approach to be followed including sample size, how the sample was determined, including assumptions made in making this determination, efficacy endpoints (primary as well as secondary) and safety endpoints.

    Statistical analysis: Give complete details of how the results will be analyzed and reported along with the description of statistical tests to be used to analyze the primary and secondary endpoints defined above. Describe the level of significance, statistical tests to be used and the methods used formissing data: method of evaluation ofdatafor treatment failures, non- compliance, and Subject withdrawals: rationale and conditions for any interim analysis if planned.

    DescribestatisticalconsiderationsforPharmacokinetic(PK)analysis,ifapplicable

15. Undertakingbythe investigators

16. Appendices:Provideastudy synopsis, copiesofthe informedconsent documents (patients

    information sheet, informed consent form etc.): CRF and other data collection forms; a summaryof relevant pre-clinical safety information and any other documents in the clinical protocol.

ANNEXURE.7: **FORMIII**

Form III

Check list for verification of proposals submitted to Institute Ethics committee (Human studies)

For official use only *Proposal No.*

	Yes	No	NA	Comments
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. If the study is a replication of a previous study, is it justified?				
3. Can the intervention studied be practically implemented?				
4. Is there provision for dissemination of results of the research?				
5. Has the research protocol been approved by a competent body?				
6. Should the study be referred to a technical expert, policy maker of statistical expert? (If YES, please inform the Secretary/ERC as soon as possible, suggesting a suitable person)				
7. Are the objectives stated clearly?				
8. Is the study design appropriate in relation to the objectives?				
9. Are the investigators qualifications, competence and experience appropriate to conduct the study?				
10. Are the facilities at the site adequate to support the study?				
11. Is the manner in which the results of research will be reported and published ethical?				
Assessment of Risks/Benefits				
1. Is the involvement of human participants necessary to obtain the necessary information?				
2. Are the researcher qualifications, competence, and experience suitable to ensure safe conduct of the study?				
3. Is the justification of predictable risks and inconveniences weighted against the anticipated benefits for the research participant and the concerned communities adequately?				
4. Are there any plans to withdraw or withhold standard therapy for the purpose of research and such actions if any justified?				
5. Is there provision for compensation for participants who sustain injuries?				

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	Yes	No	NA	Comments
6. Have adequate provisions been made for dealing with and reporting adverse effects?				
7. Have adequate provisions been made for safety monitoring and termination of the research project?				
Respect for the dignity of the research participants				
Informed consent				
1. Is the process for obtaining informed consent appropriate?				
2. Are the participants competent to give consent?				
3. Is the justification adequate for the intention to include individuals who cannot consent?				
4. Will dissent be respected?				
5. Is the written and oral information to be given to the research participants appropriate, adequate, complete and understandable?				
6. Do you approve the incentives offered?				
7. Is the consent given voluntarily and not due to deception, intimidation or inducement?				
Confidentiality				
1. Will the researcher collect only the minimum information/samples required to fulfill the study objectives?				
2. Is the privacy of the research participant safeguarded?				
3. Are data/sample storage and disposal procedures adequate?				
Rights of the participants				
1. Is the participant's right to unconditionally withdraw from the research at anytime safeguarded?				
2. Is there provision for participants to be informed about newly discovered risks or benefits during the study?				
3. Is there provision for the subjects to be informed of results of clinical research?				
Fair participant selection				
1. 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)?				
2. 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?				
3. Does the selection of participants stigmatize any group?				
4. Does selection of subjects favour any group?				

		No	NA	Comments
5. Is the research conducted on vulnerable individuals or groups?				
6. Is the research externally sponsored?				
7. Is the research a community research?				
8. Is the research a clinical trial?				
Responsibilities of the researcher:				
1. Is the medical care to be provided to the research participants during and after the research adequate?				
2. Has the researcher obtained permission from the relevant authorities?				
3. Are there any conflicts of interest, including payments and other rewards?				
4. Are there any other ethical / legal/ social /financial issues in the study?				

Additional Comments:

.....

.....

.....

.....

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

.....

.....

.....

.....

.....

Name of Reviewer:

Signature:

Date:

ANNEXURE.8: **FORMIV (A)**

1. CHECKLISTFORSTUDYSUBJECT'SINFORMEDCONSENTDOCUMENTS

Essential Element:

1. Statementthatthe studyinvolvesresearchand explanationofthepurposeofthe research
2. ExpecteddurationoftheSubject's participation
3. Descriptionoftheprocedures tobefollowed, includingallprocedures and
4. Descriptionofanyreasonablyforeseeablerisksordiscomfortstothesubject
5. Description of any benefits to the subject or others reasonably expected from research. If no benefit is expected subject should be made aware of this.
6. Disclosureofspecificappropriatealternativeproceduresortherapiesavailabletothe subject.
7. Statementdescribingthe extenttowhichconfidentiallyofrecordsidentifyingthesubjectwill be maintained and who will have access to subject's medical records
8. Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials)
9. Compensationand/ortreatment(s)availableto the subjectinthe eventoftrial-related injury
10. An explanation about whom to contact for trial related queries, rights of subjects and in the event of any injury.
11. Theanticipatedproratedpayment,if any,to thesubject forparticipating inthe trial
12. Subject'sresponsibilitiesonparticipationinthetrial.
13. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled
14. Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect.
15. Statement that in the case of placebo controlled trial, the placebo administered to thesubjects shall not have any therapeutic effect.
16. Anyotherpertinentinformation

Additionalelements,which mayberequired

a. Statement of foreseeable circumstances under which the subject's participation may be terminated by the Investigator without the subject's consent.

b. Additionalcoststothesubjectthat mayresultfromparticipationinthe study.

c. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by subject.

d. Statement that the subject or subject's representative will be notified in a timely mannerif significant new finding develop during the course of the research which may affect the subject's willingness to continue participation will be provided.

e. Astatement that the particulartreatment or proceduremayinvolve risks to thesubject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable

f. Approximatenumberofsubjectsenrolledinthe study

ANNEXURE.9: **FormIV(B)**

Formatofinformedconsentform forSubjects participatingin aclinicaltrial

InformedConsentformtoparticipateina clinicaltrial

Study Title:

Study Number:

Subject's Initials_____ Subject's Name _____
Dateofbirth/Age:_____
Address of Subject
Qualification
Occupation: Student or Self-Employed
or Service or Housewife or Others
(Please click as appropriate) .

Annual Incomeofthesubject:
Nameandaddress ofthe nominees and
his/her relation to the subject (for the
purpose of compensation in case oftrial
related death).
PleaseinitialBox (Subject)

(i)	IconfirmthatIhavereadandunderstoodthe informationsheet dated _____fortheabovestudy and havehad theopportunity to askquestion.	[ ]
(ii)	Iunderstood thatmy participation inthestudyis voluntary andthatIam freeto withdrawat anytime'withoutgiving any reason. Withoutmymedicalcare orlegalrightsbeingaffected.	[ ]
(iii)	Iunderstandthatthesponsoroftheclinicaltrial,othersworkingonthe sponsor 'sbehalf'theEthicsCommitteeandtheregulatoryauthoritieswillnotneed my permissiontolookatmyhealthrecordsbothinrespectofthecurrentstudy and anyfurtherresearchthatmaybeconductedinrelationtoit,evenifI withdraw	[ ]

fromthetrial.Iagreeto thisaccess. However,Iunderstand that my identity willnotberevealedinanyinformationreleasedtothirdpartiesor published.

(iv) Iagreenot torestrict theuseof any dataor result thatarisefrom this study [ ]
Providedsuchauseonlyforscientificpurpose(s)

(v) Iagreeto takepartin theabovestudy.

Signature (or Thumb impression of the subject/legally acceptable Representative:_____

Date _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

StudyInvestigator's Name:_____

Signatureof the Witness_____Date: _____/_____/_____

Signature of the Witness _____Date _____/_____/_____

Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject his or her attendant.

ANNEXURE.10: **FORMV**

UNDERTAKINGBYTHE INVESTIGATOR

1. Full name, address and title of the Principal Investigator (or Investigator(s) when there is no Principal Investigator)

2. Name and address of the medical college, hospital or other facility where the clinical trialwill be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, and /or other statement(s) of qualification(s)

3. Nameandaddressof allclinicallaboratory facilitiestobeusedinthe study.

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigation (s).

6. Protocol Title and study number (if any) of the clinical trial to be conducted by the Investigator.

7. Commitments:

(i) I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.

(ii) I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the sponsor and prior review and documented approval / favorable opinion from the Ethics Committee of the amendment, expect where necessary to eliminate an immediate hazard(s) to the trial subjects or when the changes(s) involved are only logistical or administrative in nature.

(iii) Iagreeto personally conductand/orsupervisetheclinicaltrial atmy site.

(iv) I agree to inform all trial subject, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.

(v) I agree to report to the sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory and GCP guidelines.

(vi) I have read and understood the information in the Investigator' brochure, including the potential risks and side effects of the drug.

(vii) Iagreetoensurethatallassociates,colleaguesandemployeesassistingintheconduct of the study are suitably qualified and experienced and they have been informedabout obligations in meeting their commitments in the trial.

(viii) I agree to maintain adequate and accurate records and to make those records available for audit/inspection by the sponsor, Ethics Committee, Licensing Authority or their authorized representative, in accordance with regulatory and GCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the sponsor.

(ix) I agree to promptly report to the Ethics Committee all changes in the clinical trial activities and all unanticipated problems involving risk to human subjects or others.

(x) I agree to inform all serious adverse events to the Central Licensing Authority, sponsor as well as the ethics committeewithin twenty-fourhoursoftheiroccurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licensing Authority along with the report of the serious adverse event.

(xi) The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licensing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.

(xii) I will maintain confidentially of the identification of all participating study patients and assure security and confidentially of study data.

(xiii) I agree to comply with all other requirement, guidelines and statutory obligations as applicable to clinical Investigator participating in clinical trials.

SignatureofInvestigatorwithdate

ANNEXURE.11: **FormVI**

DATAELEMENTSFORREPORTINGSERIOUSADVERSEEVENTSOCCURRING IN A CLINICAL TRIAL OR BIOAVAILABILITY OR BIOEQUIVALENCE STUDY

1. Patient Details:

Initialsandotherrelevantidentifier(hospitalorout-patientdepartment(OPD)recordnumber etc)*
Gender
Ageordateofbirth Weight
Height

2 .SuspectedDrug(s):

Genericnameofthedrug*
Indication(s)forwhichsuspectdrugwasprescribedortested. Dosage form and strength.
Dailydoseandregimen(specifyunits-e.g.,mg,ml,mg/kg). Route of administration.
Startingdateandtimeofday.
Stoppingdateandtime, ordurationoftreatment

3. OtherTreatment(s):

Providethesameinformationforconcomitantdrugs(includingnon-prescriptionorOverthe Counter OTC drugs) and non-drug therapies, as for the suspected drug(s).

4.Detailsof SeriousAdverseEvent:

Full description of the event including body site and severity, as well as the criterion (or criteria) for considering the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe
a specific diagnosis for the event*
Startdate(andtime)ofonsetofevent.
Stop date (and time) or duration of event.
Dechallengeandrechallengeinformation.
Setting(e.g.,hospital, out-patientclinic, home,nursing home).

1. Outcome

   Informationonrecoveryandanysequelae;resultsofspecifictestsortreatmentthatmayhave been conducted.
   For a fatal outcome, cause of death and a comment on its possible relationship to the suspectedevent; Any post-mortem findings.
   Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.

2. DetailsabouttheInvestigator*

3. Name and Address
   Telephonenumber
   Profession(specialty)
   Dateofreportingtheevent toCentral Licensing Authority:
   Dateofreportingtheeventtoethicscommitteeoverseeingthesite: Signature of the Investigator or Sponsor

   Note: Informationmarked *mustbeprovided.

ANNEXURE.12:<u>Formatforsubmission ofStudyCompletionreportsforInvestigators</u>

1. PrincipalInvestigator details

Name

Designation

Department

Email ID

Contactnumber

2. Study details-

a. Title

b. IECNumber

c. IECApprovaldate

d. Sponsor/Grantagency

e. CTRInumber(incaseofClinical Trial):

Ifnotregistered,give reason

f. Dateofstartofstudy

g. Dateofcompletionof Study

3. Summary of work done (along with results of the study and publications from the study, if any)

4. SeriousAdverseEvents(SAEs)/anyunexpectedadverse event

WereallSAEs/unexpectedadverseeventreportedtoIEC If

yes, reference number and dates

(ifno, give reason)

WhetherreportsofSAEsatothersiteshavebeensubmitted to the

IEC IGMC Shimla

5. **Protocolamendments(ifany)**

WeretheseamendmentsapprovedbytheIEC (if

no, give reason).

6. **Protocolviolations**

Anymajor protocol violations (ifany)

Ifyes,weretheyreportedtoIEC (if

no, give reason)

7. **AnnualReportssubmitted regardingthestudy** (referenceno. anddates)

8. Signatureof PI with date

ANNEXURE.13.Formatforsubmissionof AnnualProgressReportforinvestigators

1. PrincipalInvestigator details

Name
Designation
Department
Email ID
Contactnumber

2. Study details-

a. Title
b. IECNumber
c. IECApprovaldate
d. Sponsor/Grant agency
e. CTRInumber(incaseofClinical Trial):
Ifnotregistered,givereason f.Date
of start of study
(ifnotstarted, givereason andexpectedstart date)
g.Dateoflaststatus report(if submitted)

3. Summaryofworkdone(alongwithpreliminaryfindingsand
publications from research if any)

a. Till date
b. Withinlastone year

4. SeriousAdverseEvents(SAEs)/anyunexpectedadverseevent

WereallSAEs/unexpectedadverseeventreportedtoIEC If
yes, reference number and dates
(ifno, give reason)
WhetherreportsofSAEsatothersiteshavebeensubmitted to the
IEC IGMC Shimla

5. Protocolamendmentswithin lastoneyear(ifany)

WeretheseamendmentsapprovedbytheIEC (if
no, give reason)

6. Protocolviolationswithinlastoneyear

Anymajor protocol violations (ifany)
Ifyes,weretheyreportedtoIEC(referencenumberanddates) (if no,
give reason)

7. Newinformation

Anynewinformationthatcanaltertherisk/benefitassessment (If
yes, give details)

8. Otherissues within thelast1 year

Any issues that PI wishes to report to IEC
(changeofCo-I,addition/deletionofsites,etc.) If
yes, give details

9. Signatureof PI with date

ANNEXURE.14.

Formatforresubmissionofrevisedprotocols/submissionofadditionaldocuments forInvestigators

1. PrincipalInvestigator details
Name
Designation
Department
Email ID
Contactnumber

2. Study details
Title:

ApprovalDateand Number(ifalreadyapproved):

3. Purposeofthissubmission(e.g.RevisedInformedConsentdocument,CaseReportForm; Change in Investigator, Addition/Deletion of sites etc.):

4. Submissiondetails

Sl.No.	Revision/Corrections Suggested by IEC	Correctionsdone:Yes/No	Whatcorrectionisdone? Mention.

5. Newdocumentsbeingsubmitted:

Nameofdocument-Modifications/revisionsmadeinthenewdocument(kindlyhighlightand tag the modifications/ revisions)
Or

Detailsaboutanynew informationbeingprovidedtotheIEC:

5. Signatureof PI with date