INDIRA GANDHI MEDICAL COLLEGE
SHIMLA

SCHEDULE OF PROCEDURE
INSTITUTIONAL ETHICS
COMMITTEE

CHECKLIST FOR SUBMISSION FOR REGISTRATION OF ETHICS COMMITTEE

#	Documents required to be submitted	Status		Page No
		Yes	No.	----
1.	Application for registration in accordance as specified Appendix VII of schedule Y	✓		1
2.	Name of the Ethics Committee	✓		14+15
3.	Authority under which the Ethics Committee has been constituted	✓		2
4.	Membership requirement of the Ethics Committee	✓		3
5.	The terms of reference of the committee	✓		31
6.	Documents, if any, proving that the members of the committee are conversant with provisions of clinical trials as per the provisions of D&C Rules and good clinical practice guidelines for clinical trials in India.	✓		2
7.	Conditions of appointment and the quorum required.	✓		2
8.	Procedure for resignation, replacement or removal of members.	✓		5
9.	Address of the office of the Ethics Committee.	✓		16
10.	Name, address, qualification, organizational title, telephone number, fax number, email, mailing address and brief profile of the Chairman.	✓		16
11.	Name: qualification, organizational title, telephone number, fax number, e-mail, and mailing address of the members of the ethics committee. The information shall also include member's specialit y (primary, scientific or non scientific), member's affiliation with institution and patient group representation, if any.	✓		2
12.	Details of the supporting staff.	✓	✓	
13.	In the case of ethics Committee existing before 08.02.2013, following should be submitted-			
	a) Types of clinical research reviewed by the committee (e.g. pharmaceuticals, devices, epidemiological, retrospective, herbals etc).			
	b) Documents reviewed for every clinical trial protocol including informed Consent documents.			
	c) Information in respect of number of meetings of the committee band documentation of the minutes of meetings of these committees concerning clinical trials.			
	d) Information regarding review of serious adverse events reported during the conduct of the trial.			
14.	The standard operating procedures to be followed by the committee in general.	✓		1-30
15.	Standard operating procedures to be followed by the committee for vulnerable population.	✓		2,4.10
16.	Policy regarding training for new and existing committee members along with standard operating procedures.	✓		3,4.10
17.	Policy to monitor or prevent the conflict of interest along with standard operating procedures.	✓		8
18.	If the committee has been audited or inspected before, give details.		✓	
19.	Undertaking by the committee as per the format Annexed.	✓		

ESTABLISHING AND CONSTITUTING THE INSTITUTIONAL ETHICS COMMITTEE

1. PURPOSE

To establish and constitute INSTITITIONAL ETHICS COMMITTEE (IEC), IGMC SHIMLA

2. SCOPE

Applicable to IGMC Shimla

3. PROCEDURE

Principal, IGMC will purpose the chairman and member Secretary for IEC

4.3 Chairman & Member Secretary will confirm their acceptance to the principal by providing all the required information for membership (Document 2)

4.5 The Principal will ensure that the IEC is established in accordance with the applicable laws and regulations of the state, country and in accordance with the value and principles of communities they serve (Document 3)

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

4.7 At regular intervals, Principal will review the functioning of IEC.

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

ESTABLISHING AND CONSTITUTING THE INSTITUTIONAL ETHICS COMMITTEE

1. PURPOSE

To appoint suitable members for the IEC, IGMC Shimla

2. SCOPE

Applicable to IGMC Shimla.

3. RESPONSIBILITY

Principal, IGMC Shimla and Chairman are responsible for implementing the SOP

4. PROCEDURE

4.1 Principal in consultation with the Chairman will propose the member of IEC, who have the qualification and experience as per appendix VIII of CDSCO & send them to secretary health & family welfare for proper orders.

4.2 When needed, IEC will invite subject experts to offer their views.

4.3 The appointment of an IEC member will be for 3 years.

4.4 During this term principal can recommend disqualification of any member if, the contribution is not adequate and/or there is long period of member's non availability and send the case to Secretary, Health & Family Welfare Govt. of H.P. for proper orders.

4.5 Member will have the right to discontinue from membership of IEC after giving written notice at least one month in advance.

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

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

4.8 Principal can nominate IEC member to undergo orientation programme in national and international developments in ethics from time to time

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

4.10 In case of any study involving vulnerable population like HIV, Females, appropriate persons from the vulnerable population will be invited as member to safeguard their interest.

ESTABLISHING AND CONSTITUTING THE INSTITUTIONAL ETHICS COMMITTEE

1. PURPOSE

To hold regular Ethics Committee meetings.

2. SCOPE

Applicable to IGMC Shimla

3. RESPONSIBILITY

The Chairman and Member Secretary are responsible for implementing this SOP

4. PROCEDURE

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

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

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

4.4 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)

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

4.6 Minutes of the IEC meetings, all the proceedings and deliberation will be documented.

4.7 Signatures of the Chairman and the Member Secretary & all present members will be obtained on the minutes of the meeting document, The minutes will be circulated to all guides /HOD in case of student/thesis protocols.

4.8 Applicant, sponsor or investigator may be invited to present the proposal or elaborate on specific issues.

4.9 Independent experts may be invited to the meeting or to provide written comment, subject to applicable confidentiality agreement. They will not have a role decision making.

4.10 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 and Rule 122DA, 122AA, 122DAC,122DD, 122E and schedule Y of drugs & Cosmetic rule 1945 and as amended from time to time.

ESTABLISHING AND CONSTITUTING THE INSTITUTIONAL ETHICS COMMITTEE

1. PURPOSE

To submit a research proposal for review by IEC.

2. SCOPE

Applicable to Principal Investigators from IGMC Shimla

3. RESPONSIBILITY

All investigators are responsible for implementing this SOP. Every protocol or amendment submitted 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 after the approval needs to be submitted

4. PROCEDURE

4.1 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 No: IA). All research proposals must be submitted in English language only. For clinical drug trials the proposal has to be sent as per performa (form II). For MD/MS/DM/M.Ch/Ph.D candidates (for Thesis protocols or Dissertation protocols /MBBS student projects) {Form IB}

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

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

4.4 Eight 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.

4.5 Receipt of the application will be acknowledged by the IEC office.

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

4.7 Every research proposal will have to pay a fee as under

a. For drug trials a sum 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)

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

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

ESTABLISHING AND CONSTITUTING THE INSTITUTIONAL ETHICS COMMITTEE

1. PURPOSE

To check the research proposals submitted by the investigators for completeness.

2. SCOPE

Applicable to IGMC Shimla.

3. RESPONSIBILITY

The office of Member Secretary is responsible for implementing this SOP.

4. PROCEDURE

4.1 Every proposal will be collected and complied by the institute Ethics Committee office.

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

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

4.4 The supporting staff available to the Ethics committee will be

- Clerk (Record Keeper) 1 No.
- Data Entry Operator 1 No.
- Class IV 1 No.

4.5 The office of Members-Secretary IEC will be located in the premises of sr. Med. Supdt, IGH Shimla.

ESTABLISHING AND CONSTITUTING THE INSTITUTIONAL ETHICS COMMITTEE

1. PURPOSE

To review the research proposals submitted by the investigators both scientifically and ethically.

2. SCOPE

Applicable to IGMC Shimla

3. RESPONSIBILITY

All members of IEC are responsible for implementing this SOP.

4. PROCEDURE

4.1 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.

4.2 Al 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.

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

4.4 Expert opinion of additional members would be obtained if necessary.

ESTABLISHING AND CONSTITUTING THE INSTITUTIONAL ETHICS COMMITTEE

1. PURPOSE

To provide expedited review and approval of a research proposal

2. SCOPE

Applicable to the members of IEC of IGMC Shimla.

3. RESPONSIBILITY

All members of Ethics Sub-Committee are responsible for implementing this SOP.

4. PROCEDURE

4.1 IEC will receive and consider the proposals for expedited review and approval for the studies having/involving:

i. No risk to trial participants.

ii. Re examination of a proposal already examined by the IEC.

iii. Study of minor nature like the examination of case records.

iv. 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.

All other proposals which do not comply with the above criteria will be reviewed in the Regular Ethics Committee meeting.

4.2 All expedited approvals will be given in a meeting of the Sub-Committee of five members (nominated by the Principal including Chairman & member secretary) All the five members including the Member Secretary should be present for the meeting

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

ESTABLISHING AND CONSTITUTING THE INSTITUTIONAL ETHICS COMMITTEE

1. PURPOSE

To make a decision regarding approval of the submitted research proposal.

2. SCOPE

Applicable to the IEC of IGMC Shimla

3. RESPONSIBILITY

All members of IEC are responsible for implementing this SOP.

4. PROCEDURE

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

4.1.1. 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.

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

4.1.3 A decision will only be taken when sufficient time has been allowed for the review.

4.1.4 Decision will only be taken at meeting where a quoram (eg. Five in a Committee of 10) is complete after ensuring that quoram is as per appendix VIII of Y schedule.

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

4.1.6 Only IEC members who participated in review and discussion will participate in decision making.

4.1.7 Wherever possible the decision will be arrived through consensus and not by vote, but when a consensus appears unlikely voting can be resorted to.

4.1.8 Decision will specify the conditional decision if any, with clear suggestions and re-review procedure.

4.1.9 Rejection of proposal will be supported by clearly stated reasons.

ESTABLISHING AND CONSTITUTING THE INSTITUTIONAL ETHICS COMMITTEE

1. PURPOSE

To communicate the decision of IEC to the applicant.

2. SCOPE

Applicable to the IEC of IGMC Shimla

3. RESPONSIBILITY

Member Secretary is responsible for implementing this SOP.

4. PROCEDURE

4.1. 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-5). All the approval 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.

4.2. The communication of the decision will include:

- Name and address of IEC.

- The date and place of decision.

- The name and designation of the applicant.

- Title of the research proposal reviewed

- The clear identification of protocol no., version no., date, amendment no. date.

- A clear statement of decision reached.

- Any advice by the IEC to the applicant.

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

- In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.

- Signature of the member secretary with date.

ESTABLISHING AND CONSTITUTING THE INSTITUTIONAL ETHICS COMMITTEE

1. PURPOSE

To carry out the follow-up of the research proposals.

2. SCOPE

Applicable to the IEC of IGMC Shimla

3. RESPONSIBILITY

All members of IEC and the investigators are responsible for implementing this SOP.

4. PROCEDURE

4.1. 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.

4.2. Progress of all the research proposals will be followed at regular interval of once a year. But in special situations, IEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.

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

4.4. Following instances and events will require the follow-up review:

4.4.1. Any protocol amendment likely to affect rights, safety or well being of research subject of conduct of study.

4.4.2. Serious or unexpected ADR related to study or product, action taken by Investigator, sponsor and Regulatory authority.

4.4.3. Any event/ information that may affect the benefit/risk ratio of the study.

4.5. A decision of follow up review will be issued and communicated to the applicant indicating modification/suspension/termination of the project.

4.6. In case of premature suspension/termination, the applicant must notify the IEC of the reasons for the suspension/termination with a summary of the result.

4.7. Applicant must inform the time of completion of study and must send the result summary to IEC. IEC must receive a copy of final summary of study completed from the applicant.

ESTABLISHING AND CONSTITUTING THE INSTITUTIONAL ETHICS COMMITTEE

1. PURPOSE

To archive the study related documents, proceedings and communications.

2. SCOPE

Applicable to the IEC of IGMC Shimla

3. RESPONSIBILITY

The Member Secretary is responsible for implementing this SOP.

4. PROCEDURE

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

4.2.Only persons, who are authorized by the chairman of IEC will have the access to the various documents.

4.3. 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.

4.4. No documents (except agenda) will be retained by any IEC member.

4.5. 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.

4.6. Following documents will be filed and archived with proper label on the top of file for easy identification of proposal.

4.6.1. The constitution, written SOPs of the IEC, and regular (annual) reports.

4.6.2 The curriculum vitae of all IEC members.

4.6.3. A record of all income and expenses if any, of the IEC, including allowances and reimbursements made to the secretariat and IEC members.

4.6.4. The published guideline for submission established by the IEC.

4.6.5 The agenda of the IEC meetings. The minutes of the IEC meetings.

4.6.6. One copy of all the material submitted by an applicant.

4.6.7. A copy of the decision & any advice or requirements sent to an applicant.

4.6.8 All written documentation received during the follow-up.

4.6.9. The notification of completion, premature termination of study.

4.6.10 The final summary or final report of the study.

Letter Ref: No:

Document -1

From

Date:

Principal
IGMC Shimla

To

Sub:- **Constitution of Institute Ethics Committee (Human studies)**

Dear Sir/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.

On receipt of your acceptance, the name will be sent proper orders from Govt. of H.P.

Your Sincerely,

Signature:-

Name:

Document -2

From

……
……

To

Principal,

IGMC, Shimla

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

Dear Sir/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.

I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel.

I herewith enclose my C.V.

Thanking you,

Your Sincerely,

Signature…….

Name of the Member……. Date:

Address:

Telephone No: Off:

Res:

Email:

Government of Himachal Pradesh
Department of Medical Education

NO: Health-B(14)-1/2005-Part-I Dated:Shimla-2 the 14/09/2018.

NOTIFICATION.

In supersession of all previous notifications issued in this regard, the Governor, Himachal Pradesh is pleased to constitute an "Ethics Committee" consisting of following members for smooth functioning developmental activities in IGMC, Shimla:-

S. NO	Name	Post.
1.	Dr. R.K. Kaushal, Ex. Professor and HOD Paediatrics, IGMC, Shimla.	Chairperson.
2.	Sh. Sarabjit Singh Bobby R/o 150 Lower Bazar, Shimla.	Member Layperson.
3.	Mrs. Kalpna Sanghaik, Social worker, Department of Radiotherapy, IGMC, Shimla.	Member NGO
4.	Sh. Shashi Kumar Shishoo, H.P. High court, Shimla.	Member Lawyer.
5.	Dr. Sanju Karol, Professor, Department of Economics, H.P. University, Shimla.	Member Social Sciences.
6.	Dr. P.K. Kaundal, Professor, Department of Pharmacology, IGMC, Shimla.	Member Basic Sciences.
7.	Dr. Punit Mahajan, Associate Professor, Department of Surgery, IGMC, Shimla.	Member Clinical
8.	Dr. Parmod Kumar Jaret, Associate Professor, Department of Medicine, IGMC, Shimla.	Member Clinical
9.	Dr. Anmol Gupta, Professor, Department of Community Medicine, IGMC, Shimla.	Member Epidemiologist.
10.	Dr. Anupam Prasher, Professor, Department of Community Medicine, IGMC, Shimla.	Member Secretary.

2/-

2. The main functions of the above Committee will be as under:-

(i) Research relating activities which involve human aspects.

(ii) Thorough examination of the projects.

(iii) Functioning and teaching of UGs/ PGs students in the Institution.

(iv) Better Hospital Services.

BY ORDER.

Addl. Chief Secretary(Health) to the
Government of Himachal Pradesh.

Endst NO:As above Dated:Shimla-2 the /09/2018.

Copy to:-

1. The Director, Medical Education and Research, H.P. Shimla-9 for information and necessary action.
2. The Principal, IGMC, Shimla.
3. The Principal, Dr. RPGMC, Tanda at Kangra, HP.
4. To all concerned.
5. Medical Superintendent, IGMC, Shimla.

14/9/18

Special Secretary(Health) to the
Government of Himachal Pradesh.

Medsupdt
IGMC
15.9.18

DOCUMENT V

Format for Approval of Ethics Committee

To

Dr.

Dear Dr._____

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

The following documents were reviewed:

a. Trial protocol (including protocol amendments), dated_____ version no (s)_____
b. Patient Information Sheet and Informed Consent Form (including updated if any) in English and/or vernacular language.
c. Investigator's Brochure, dated _____ version no._____
d. Proposed methods for the patient accrual including advertisement (s) etc. proposed to be used for the purpose.
e. Principal Investigator's current CV.
f. Insurance Policy/Compensation for participation and for serious adverse events occurring during the study participation.
g. Investigator's Agreement with the Sponsor.
h. Investigator's Undertaking

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

_____ Chairman of the Ethics Committee

_____ Member secretary of the Ethics Committee

_____ Name of each member with designation

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

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

Yours sincerely

Member Secretary, Ethics Committee.

Form IA

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

Kindly submit 8 copies of proforma and consent forms in English & Hindi to the Member Secretary, Institutional Ethics Committee (Human Studies), IGMC Shimla

1. Title of the project:
2. Name of the investigators/co-investigators with designation & department:
3. Number of projects already with the investigators/co-investigators:
4. Date of approval by IGMC Shimla
5. Sources of funding
6. Objectives of the study:
7. Justification for the conduct of the study:
8. Methodology: It should provide details of the number of patients, inclusion criteria, exclusion criteria, control(s), study design, dosages of drug, duration of treatment, investigations to be done etc:
9. Permission from Drug Controller General of India (DCGI) if applicable
10. Costs involved (Appx. In Rs)
    a) Investigations b) Disposables
    c) Exempted d) Drugs/Contrast Media
11. Ethical issues involved in the study:
    less than minimal risk / more than minimal risk to the study subjects (for guidance please consult ICMR guidelines.
12. Do you need exemption from obtaining Informed Consent from study subjects- if so give justifications.
13. Whether Consent forms part1 and 2 in English and in local language are enclosed?
14. Documents attached
    (a) Brief CV of investigators (including no. of projects with him/her)-Needed only for investigator/s from outside IGMC Shimla Brochure
    (b) Investigator's Brochure
    (c) Others
15. Conflict of interest for any other investigator(s) (if yes, please explain in 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)

    Signature of the Investigators:

    Signature of the Head of theDepartment

    (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)

Form IB

Proforma to be submitted to the IGMC Shimla Ethics Committee (Human studies) (for MD/MS/DM/M.Ch/Ph.D (for Thesis or Dissertation/MBBS student projects)

Kindly submit 7 copies of proforma and consent forms in English & Hindi to the member Secretary, Institute Ethics Committee (Human Studies), IGMC Shimla

1. Title of the project:
2. Name and Department /address of the investigators:
3. Number of Faculty (Guide/Co-guide) with designation & department:
4. Date of approval by Institute Research Council/ Scientific Advisory
5. Sources of funding
6. Objectives of the study:
7. Justification for the conduct of the study:
8. Methodology: It should provide details of number of patients, inclusion criteria, exclusion criteria, control(s), study design, dosages of drug duration of treatment, investigations to be done etc:
9. Permission from Drug Controller General of India (DCGI) if applicable
10. Ethical issues involved in the study:
    No risk/less than minimal risk / more than minimal risk to the study subjects (for guidance please consult ICMR guidelines.- at IGMC Shimla).
11. Do you need exemption from obtaining Informed Consent from study subjects- if so give justifications.
12. Whether Consent forms part1 and 2 in English and in local language are enclosed?
13. Conflict of interest for any other investigator(s) (if yes, please explain in brief)
14. We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirement of the ICMR guidelines (2017)

    Signature of the Investigators:

    Signature of the Head of theDepartment

    (**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)

Form II

CONTENTS OF THE PROPOSED PROTOCOL FOR CONDUCTING CLINICAL TRIALS

1. Title Page

a. Full title of the clinical study.

b. Protocol/Study number, and protocol version number with date

c. The IND name/number of the investigational drug

d. Compete name and address of the Sponsor and contract research organization if any

e. List of the Investigators who are conducting the study, their respective institutional affiliations and site locations

f. Name (s) of clinical laboratories an d other departments and /or facilities participating in the study.

2. Table of Contents

A complete Table of Contents including a list of all Appendices.

1. Background and Introduction

a. Preclinical experience

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 in the particular included by the protocol should be provided.

3. Study Objective (s) (primary as well as secondary) and their logical relations to the study design.

3. Study Design

a. Overview of the study Design: Including a description of the type study (i.e. double- blind, multicentre, placebo controlled, etc), a detail of the specific treatment groups and number of study Subject in each group and investigative site, Subject number assignment, and the type, sequence and duration of study periods.

b. Flow chart of the study

c. A brief description of the methods and procedures to be used during the study.

d. Discussion of Study design: This discussion details the rationale for the design chosen for 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. Inclusion Criteria

b. Exclusion Criteria

7. Study Assessments – plan procedures and methods to be described in 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.

   Each visit should be described separately as visit I, Visit 2, 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. Dosing schedule (dose, frequency, and duration of the experimental treatment) 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. Possible drug interactions
   e. Concomitant therapy: the drugs that are permitted during the study and conditions under which they may be used are detailed here. Describe the drugs that a subject is not allowed 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. Unblinding procedures: If the study is blinded , the circumstances in which unblinding may be done and the mechanism to be used for unblinding should be given

10. Adverse Events Description of expected adverse events should be given.

11. Ethical Considerations: Give the Summary of:
    a. Risk/benefit assessment:
    b. Ethics Committee review and communications
    c. Informed consent process
    d. Statement of subject confidentially including ownership of date coding procedures
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. Investigational Product Management
    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. The precise dosing required during the study)
    c. Method of assigning treatments to subjects and the Subject identification code numbering system
    e. Storage conditions for study substances
    f. Investigational product accountability: Describe instructions for the receipt, storage, dispensation, and return of the investigational products to ensure a complete accounting of all investigational products received, dispensed, and returned /destroyed.
    g. Describe policy and procedure for handling unused investigational products.

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 for missing data: method of evaluation of data for treatment failures, non compliance, and Subject withdrawals: Describe statistical considerations for Pharmacokinetic (PK) analysis, if applicable
15. Undertaking by the investigators
16. Appendices: Provide a study synopsis, copies of the informed consent documents (patients information sheet, informed consent form etc.): CRF and other data collection forms; a summary of relevant pre-clinical safety information and any other documents in the clinical protocol.

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 or 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?				

	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:

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

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Name of Reviewer:

Signature:

Date:

FORM IV (A)

1. CHECKLIST FOR STUDY SUBJECT's INFORMED CONSENTDOCUMENTS

1.1 Essential Element:

1. Statement that the study involves research and explanation of the purpose of the research
2. Expected duration of the Subject's participation
3. Description of the procedures to be followed, including all procedures and
4. Description of any reasonably foreseeable risks or discomforts to the subject
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. Disclosure of specific appropriate alternative procedures or therapies available to the subject.
7. Statement describing the extent to which confidentially of records identifying the subject will 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. Compensation and/or treatment(s)available to the subject in the event of trial-related injury
10. An explanation about whom to contact for trial related queries, rights of subjects and in the event of any injury.
11. The anticipated prorated payment, if any, to the subject for participating in the trial
12. Subject's responsibilities on participation in the trial.
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. Any other pertinent information

1.2 Additional elements, which may be required

a. Statement of foreseeable circumstances under which the subject's participation may be terminated by the Investigator without the subject's consent.
b. Additional costs to the subject that may result from participation in the 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 manner if significant new finding develop during the course of the research which may affect the subject's willingness to continue participation will be provided.
e. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
f. Approximate number of subjects enrolled in the study

CONSENT FORM (B)

Informed Consent form to participate in a clinical trial

Study Title:

Study Number:

Subject's Initials_____ Subject's Name _____

Date of birth/Age:_____

Please initial Box (Subject)

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask question. [ ]

(ii) I understood that my participation in the study is voluntary and that I am free to withdraw at any time' without giving any reason. Without my medical care or legal rights being affected. [ ]

(iii) I understand that the sponsor of the clinical trial, others working on the sponsor 's behalf' the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or result that arise from this study Provided such a use only for scientific purpose(s) [ ]

(v) I agree to take part in the above study.

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

Date _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Study Investigator's Name:_____

Signature of the Witness_____ Date: _____/_____/_____

Signature of the Witness _____Date _____/_____/_____

FORM V

UNDERTAKING BY THE 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 trial will 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. Name and address of all clinical laboratory facilities to be used in the 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 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) I agree to personally conduct and/or supervise the clinical trial at my site.

   (iv) I agree to inform all subjects, that the drugs are being used for investigational purposes and I will ensure that the requirements to obtaining informed consent and ethics committee review and approval specified in the GCP guidelines.

   (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) I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about 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 unexpected serious adverse events to the sponsor as well as the Ethics Committee within seven days of their occurrence.

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

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

8. Signature of Investigator with date