Protocol for approval by Ethics Committee, KLE University

Title, version no. date , Principal Investigator's name

Protocol Title :

Principal Investigator:

Co- Investigator/s:

S. No.	***Enclosures :***	***Page Nos.***
1	Face sheet	
2	Undertaking of Principal, Co-investigator and Collaborators	
3	Brief Bio-data of investigators	
4	Role of Investigators	
5	Certification regarding conflict of interest, if applicable	
6	Summary of study protocol	
7	Detailed protocol	
8	Participant Information sheet	
9	Informed Consent Document	
10	Funding Agency / sponsor's letter	
11	GCP Training Certificate of Principal Investigator/ Co-Investigators/Collaborators	
12	Any other relevant documents	

Title, version no. date , Principal Investigator's name (Put as header on all pages)

'FACE SHEET' of the Protocol

1. Title of the Project
   (It should be concise & self-explanatory)

To be filled by office
• Protocol No.
• Date of Receipt
• Date/s of Review
• Status - New/Revised/Amendment
• Date of Start
• Duration of the study

2. Name, affiliation, official postal address, telephone nos., e-mail address of the Principal Investigator / Co-ordinator. *(If it is a multicentric study, - who would be responsible for implementation of the protocol)*

3.	**Name and address of the Institution / Organization responsible for conduct / coordination of the protocol.**	3(a)	**Name and address of the officer responsible for Institutional Supervision**
4.	**Name and address of the Funding / Sponsoring Institution/CRO**	4(a)	**Name and address of the Officer-in-charge of the funding / Sponsoring Institution / CRO**

5. Name and address of the auditor / monitor of the Protocol:
   Title, version no. date , Principal Investigator's name
6. Comments / Recommendations of the SAC / SRC / Technical Experts:
   (Attach Minutes / Letter, Page No.)
7. Comments / Recommendations of the Statistician (If Applicable):
   (Attach letter, Page No.)
8. To be answered by the PI / Co-ordinator

a.	Does the protocol fall under exempt category? *(If yes, give reasons on separate sheet)*	Yes	No

b.	Is request made for obtaining waiver from informed consent? *(If yes, give reasons on separate sheet, Page No.)*	Yes	No
c.	Is request made for expedited review? *(If yes, give reasons on separate sheet, Page No.)*	Yes	No
d.	Does the protocol involve Human participants *(If yes, will it include)*	Yes	No
	i) body fluids *(if yes, give details)* *i)* Control – *ii)* Study group –	Yes	No
	ii) Administration of an investigational substance / implantation of a device *(if yes, provide name of the drug / substance / device etc. and its manufacture's name and address) (Also, clearance from the DCGI, if relevant)*	Yes	No
	iii) exposure to ionizing radiation	Yes	No
	iv) Use of genetically engineered products (if yes, give details of the product, and appropriate clearances from the DBT, GEAC, DCGI, etc.)	Yes	No
e.	Does the protocol involve inclusion of vulnerable participants *(If yes, special precautions proposed to safeguard their rights and interests shall be documented on separate sheet)*	Yes	No

It is certified that the statements made herein are true, complete and accurate to the best of my/our knowledge. I am aware that false, fictitious or fraudulent statements or claims may subject me/us to criminal, civil or administrative penalties. I/we agree to accept responsibility for the scientific conduct of the protocol and to provide required progress reports if the permission is granted as a result of this application.

Title, version no. date , Principal Investigator's name

Signature of Investigator:

Date:

Place:

1. 12 copies of all the documents, neatly typed, numbered and should be submitted in bound files.
2. Title of the protocol should be put as a header with the name of Principal Investigator. Versions if any, and date should be incorporated. e.g. all new proposals will bear Version No and date.
3. All pages must be serially numbered and put as footer on the right side of the page.
4. Any incomplete proposal will not be considered for the meeting. Any blank left in the study proposal (example: signatures), should be justified.

5. All the PIs are instructed to read the ICMR guidelines for Biomedical Research on Human Participants – 2006 before filling the form.

UNDERTAKING BY INVESTIGATORS AND CO- INVESTIGATORS

Study Proposal entitled "……"

1. We have read the ICMR's Guidelines for ethical conduct of research involving human participants, and are familiar with our duties / obligations to ensure safety, welfare of participants enrolled in the study and confidentiality of the data. The study would start only after obtaining the approval of Institutional Ethical Committee. We have also read the guidelines for good clinical practice issued by DGHS, Government of India and will follow them in our research on human participants. We would be responsible for obtaining the informed consent of participants before enrolling them in the study.

2. The Principal investigator, Co-investigators and the Clinical Collaborators will take the full responsibility for the safety of the study participants. Also, the patient care and clinical management will be the joint responsibility of the collaborator, principal investigator and co-investigator.

3. We will follow all the restrictions, if any, laid down by the Ethics Committee; and seek its approval, if there is any deviation in the protocol / procedure of consent. We will report all adverse events, which are required to be reported, and will maintain all records as required. We will honor all obligations as accepted in the consent form.

4. There is no conflict of interest of any kind in carrying out the proposed study. We will not receive any personal, direct or indirect financial benefit from the conduct of this study

5. It is also certified that the statements made herein are true, complete and accurate to the best of my/our knowledge. I am aware that any false, fictitious or fraudulent statements or claims may subject us to criminal, civil, or administrative penalties. We agree to accept responsibility for the scientific conduct of the protocol and to provide required progress reports if the permission is granted as a result of this application.

Signature of Principal Investigator	Signature of Co- Investigator
Date : _____	Date : _____
Name :……	Name:……..…….
Address : …….	Address:……

Format for Summary and Detailed Protocol

Summary of Protocol
Introduction:
Rationale:
Objectives of the study:
Inclusion criteria:
Exclusion criteria:
Methodology (including Study Duration):
Implications of the study:
Expected Outcome:

……

Detailed Protocol
Introduction and Rationale:
Objectives of the study:
Overall and Specific:
Participants enrolled for this study:
Exclusion criteria:
Methodology (including Study Duration):
Study Design, Sample Size, Study Setting
Expected Outcome:
References:

Guidelines for reviewing Participant Information Sheet and Informed Consent Document

The following points should be considered while reviewing the Participant Information Sheet and Informed Consent Document

1) Participant Information Sheet Process

- The EC Members should check whether the Participant Information Sheet and Informed Consent Document are as per the norms provided to the Principal Investigator (AF/IEC/03/08/V7.1). The Participant Information Sheet (PIS) and Informed Consent Document (ICD) should be congruent with the Application and the research study.
- To see whether the information in the consent form is a reflection of Investigator's communication with the study participant.
- Final comprehensive information of the study may also be given to the participants.
- Information provided in Participant Information Sheet is in simple language (easily understood by lay person), with no scientific jargon and yet complete and updated. Informed consent documents should be written using language at the reading level and technical level of the participant.
- Consent document is written at the 8th grade reading level.
- Because research participants come from a variety of backgrounds and educational levels and are frequently under physical and emotional stress, it is important that Participant Information Sheet/consent form is easy to understand. If a medical term is essential, lay language definition is included . .
- No informed consent, whether oral or written, may include any language through which the research participant or the representative is made to waive or appear to waive any of the research participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
- Investigator/Co-Investigator has to obtain consent from the potential participants.
- The individual taking the consent should be well versed, sufficiently trained and knowledgeable about the study to answer any questions or appropriately refer questions that may exceed their expertise put forth by the potential study participants.
- The individual obtaining consent can unintentionally influence a research participants decision to participate in research, hence every effort should be taken to avoid undue influence.
- Maintaining privacy and the place/setting in which the consent is obtained is of paramount importance. The consent process should be conducted individually and in areas where the discussion is not overheard, there is no peer pressure and or/inattention and no unwanted stress or anxiety.
- The timing of the consent process may have a negative impact on the potential research participant's ability to make a considered decision.
- All research participants must be given the Participant Information Sheet and the Informed Consent Document to take it home (If they desire's so)to discuss it with their family members, doctor and friends. Allowing the research participants sufficient time may improve the quality of the informed consent process. In case of studies pertaining to delivery/labor, informed consent should be obtained in the prenatal visit and reconsent may be taken.

- Investigator, study co-ordinator, social worker or any other team member of the research study should sit face-to-face with the potential participant read/discuss the Participant Information Sheet/Informed Consent Document

Telephone surveys/interveiw

- Describe how personal information will remain confidential. In the case where the data collected contains identifying information (e.g., interview tapes, contact information for follow up studies, clinical history with age and name and other identifiable information), describe with whom, for how long, how the data will be stored, and that when the data is no longer required the data will be appropriately destroyed. If the data are anonymous, this statement may be omitted.

  All records identifying the participants will be kept confidential and, to the extent permitted by the applicable laws and regulations, will not be made publicly available. The study doctor and research team will use personal information about you to conduct this study. This may include your name, address, medical history and information from your study visits. However, this personal information is not included in the study data that will be forwarded to the sponsor or sponsor representatives. You will be identified by a coded number in any reports of publications produced from this study (study data).

  This is important in studies like in Reproductive tract infections, gene studies etc.
- Describe who has access to the data, where the data is and how it will be stored securely.

  To confirm that the study data collected about you is correct and related to you, selected people working for the sponsor, as well as representatives of government regulatory authorities and ethics committees will have access to your personal information at the study site. These persons are required to maintain the confidentiality of your information. **By signing this document, you are authorizing such access.**

2) Informed Consent Process

The actal **process of informed consent** should:

- Give the participants significant **information** about the study.
- Make sure the participants have **enough time** to carefully read and consider all options.
- **Answer all questions** of the participants before making decision to participate.
- Explain **risks or concerns** to the participants**.**
- Make sure that all information is **understood and satisfies the participants**.
- Make sure the participants understand the study and the consent process.
- Obtain **voluntary** informed **consent** to participate.
- Make sure the participants can **freely consent without coercion, pressure or other undue influences.**
- Consent should be **informally verified on a continuing basis.**
- **Continue to inform** the participants throughout the study.
- **Continue to re -affirm** the **consent/assent** to participate throughout the study.
- CRC should write the entire narration of the complete informed Consent Process.
- **Procedures or methods** used in the informed consent process for recruitment of study participants include:A consent form
- Brochures, Pamphlets or other reading materials (i.e., letters to participants, phone pre-screening questionnaires, phone hold messages)
- Internet information
- Instruction sheets
- Audio-visual presentations
- Charts, diagrams or posters

- Discussions
- Consultation with others
- Duration of sample storage and its disposal

Techniques to improve the readability of consent forms:

- Use short sentences and paragraphs
- Limit to one thought or topic in a sentence, avoid run-on sentence
- Use simple words, less syllables in a word.
- Use common words, remove technical jargon and medical terms.
- Try to use correct basic grammar and form.
- Use "gene **transfer**" instead of "gene **therapy**" (less implied effectiveness).
- Use"**agent**" instead of "**drug**" or "**medicine** " (less implied effectiveness).
  Try to avoid the use of "**treatment**", "**therapy**" or "**therapeutic**" in studies involving gene transfer (because these words imply effectiveness)

Participant Information Sheet

Title of Project:_____
Principal Investigator: Name,
Designation,
Contact details_____

Co- Investigator(s): Name,
Designation,
Contact details_____

You are invited to take part in this research study. Research is different than routine care. Routine care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of research studies is to gain knowledge that may help future patients.

This Participant Information Sheet gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take the time to review this information carefully. You are requested to ask for an explanation of any words you do not understand. After you have read the Participant Information Sheet you are free to talk to the doctors/researchers about the study and ask them any questions you have. You will be given a copy of the participant information sheet and discuss it with your friends, family, or other doctors about your participation in this study.

If you have decided to take part in the study, you will be asked to sign the informed consent form which is along with this Participant Information Sheet. Before you sign the informed consent form, be sure you understand what the study is about, including the risks and possible benefits to you. You will be given a copy of the Participant Information Sheet and signed informed consent form for your future reference.

Please remember that your participation in this study is entirely voluntary. You are free to withdraw from the study at any point of time without affecting your medical care and services. Also, by signing the Consent form you have not waived off any rights as a participant.

You may please note that being in a research study does not take the place of routine physical examination or visits to your own doctor and should not be relied on to diagnose or treat any other medical problems.

1. What is this research study about?
2. What information is known about this type of research study?
3. Why is this research study being done?
4. Who can take part in this research study?
5. How many participants will be included for this research study?
6. What do you have to do if you agree to take part in the research study?
7. **What are the possible benefits to you by being in the research study?**

8. How will the research study be done?
9. What are the tests that will be performed on the participant/ biological sample?
10. How long will you be in the research study?
11. How long the biological samples will be stored and how will it be disposed?
12. Under what conditions will your Participation in the study be terminated?
13. What are the possible risks and inconveniences that you may face by being in the research study?
14. What happens if you are injured since you took part in this research study?
15. What are the other treatment options/alternatives to participation?
16. What will happen if you change your mind about participation in this research study?
17. How will your privacy and confidentiality be maintained?
18. Will you have to bear any Expenses or Costs by participating in the research study?
19. Whom do you call if you have questions or problems?
a. Research related
b. Regarding rights as a Participant

Please note that some questions may not be applicable to your research study, hence can be marked as Not Applicable, example Q.12 is applicable for clinical trials, Q.10 may not be applicable for basic research studies wherein the biological samples are taken at a point time.

Please contact the researchers listed below to:
Obtain more information about the study
Ask a question about the study procedures or treatments
Dr. …….
Scientist.....
Depatment.....
Phone…..

If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee through the Ethics Office. (Please feel free to address the Ethics Committee through the Ethics Office and identify yourself by the 'participant identification number' as filled in your participant enrollment form – for sensitive study like HIV)

Name of the Member Secretary
Ethics Committee,KLE University
JNMC Campus Nehrunagar Belagavi 590010
Tel.No.: 0831-2470400
Fax No.: 0831-2493099
Email : kleclinicalresearch@gmail.com
Time to contact- Office Hours

The Institutional Ethics Committee for Clinical Research comprises of a group of people like doctors, researchers, and community people (non scientific) who work towards safeguarding the rights of the study participants like you who take part in research studies undertaken at the institute

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records

Informed Consent Form

I_____have read /have had read the participant information sheet version no. ……..dated……bearing page numbers 1-….. of the research study entitled ……

The information contained in the participant information sheet regarding the nature and purpose of the study, safety, and its potential risks / benefits and expected duration of the study, and other relevant details of the study including my role as a study participant have been explained to me in the language that I understand. I have had the opportunity to ask queries, which have been clarified to my satisfaction.

I understand that my participation is voluntary and that I have the right to withdraw from the study at any time without giving any reasons for the same. This will not affect my further medical care or any legal right.

I understand that the information collected about me during the research study will be kept confidential. The representatives of sponsor/, government regulatory authorities/ethics committees may wish to examine my medical records/study related information at the study site to verify the information collected. By signing this document, I give permission to these individuals for having access to my records.

I hereby give my consent willingly to participate in this research study. I am informed that I will be/ will not be given any compensation/ reimbursement for participation in the study.

For Limited or non readers: (Illiterate participants) I have witnessed the consent procedure of the study participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Signature of Impartial witness/Legal Authorised Representative (wherever relevant) with date

Signature/Thumb impression of Study Participant with date

Name of the Witness

Name of the Study Participant

Signature of Principal Investigator with date

Signature of Person administering the consent with date

Name of the Principal Investigator

Name of the Person administering the consent

ANNEXURE: 07 **AF/IEC/07/08/V7.1**

Informed Consent Form
(For future use of stored samples)

I_____ give/do not give permission to preserve my samples to be used for any extension / modification of this study.

If any other studies planning to use these left over stored samples, are decided in future, with the appropriate permission of the Ethics Committee.

I hereby give my consent willingly for use of my samples for future studies as mentioned above.

For Limited or non readers: (Illiterate participants) I have witnessed the consent procedure of the study participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Signature of Impartial witness with date

Name of the Witness

Signature/Thumb impression of Study Participant with date

Name of the Study Participant

Signature of Principal Investigator with date

Name of the Principal Investigator

Signature of Person administering the consent with date

Name of the Person administering the consent

ANNEXURE: 08 **AF/IEC/08/08/V7.1**

Assent Form

I ……have read /have had read the participant information sheet version no. ……..dated……bearing page numbers 1-….. of the research study entitled ……

The information contained in the participant information sheet regarding the nature and purpose of the study, safety, and its potential risks / benefits and expected duration of the study, and other relevant details of the study including my role as a study participant have been explained to me in the language that I understand. I have had the opportunity to ask queries, which have been clarified to my satisfaction.

I understand that my participation is voluntary and that I have the right to withdraw from the study at any time without giving any reasons for the same. This will not affect my further medical care or any legal right.

I understand that the information collected about me during the research study will be kept confidential. The representatives of sponsor/, government regulatory authorities/ethics committees may wish to examine my medical records/study related information at the study site to verify the information collected. By signing this document, I give permission to these individuals for having access to my records.

I hereby give my assent willingly to participate in this research study.

For Limited or non readers: (Illiterate participants) I have witnessed the assent procedure of the study participant and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

Signature of Impartial witness with date

Signature/Thumb impression of Study Participant with date

Name of the Witness

Name of the Study Participant

Signature/Thumb impression of Mother/Father with date

Name of the Parent

Signature of Principal Investigator with date

Signature of Person administering the assent with date

Name of the Principal Investigator

Name of the Person administering the assent

Guide to Placebo Justification

Background conditions, such as benefits of standard treatment, risk of using placebo, risk management and disclosure should be considered. The followings are some guides to ease Board decision.

I. Benefits of standard treatment

1) Is there a standard treatment?
2) Is the standard treatment widely accepted?
3) Has efficacy of the treatment been consistently proven?
4) Are all newly diagnosed patients with this condition put in standard treatment (versus observed or other)?
5) Does the treatment act on the basic mechanism of the disease (vs. symptoms)?
6) Are most (85%) of the patients with this condition responsive to standard treatment alternatives (vs. resistant or refractory)?

If the answer of (1) to (6) are "yes", placebo is not recommended.

If any one or more answers are "no", placebo may be possible.

II. Risks of placebo

1) Is the risk of using placebo instead of treatment life threatening?
   If yes, placebo is not acceptable.
2) Is the use of placebo instead of treatment likely to lead to permanant damage?
   If yes, placebo is not acceptable
3) Is the risk of using palcebo instead of treatment likely to cause irreversible disease progression?
   If yes, placebo is not acceptable.
4) Can the use of placebo instead of treatment lead to an acute emergency?
5) Is the risk of using placebo instead of treatment the persistence of distressing symptoms?
6) Is the risk of using placebo instead of treatment severe physical discomfort or pain?
   If the answer of (4) to (6) are"yes", placebo is not acceptable unless risk management is adequate.

III. Risk management

1) Is there benefit in the overall management of the subject?
   ☐Yes, consider placebo
   ☐No, placebo not recommend.
2) Will the discontinuation of provious treatment put the participant in danger of acute relapse when transferred to placebo?
   ☐No, consider placebo
   ☐Yes, placebo not recommend.
3) Are subjects at high risk for the use of placebo excluded?
   ☐Yes, consider placebo
   ☐No, placebo not recommend.
4) Is the duration of the study the minimum necessary in relation to the action of the drug?
   ☐Yes, consider placebo
   ☐No, placebo not recommend.
5) Are there clearly defined stopping rules to withdraw the subject in case he/she does not improve?
   ☐Yes, consider placebo

☐No, placebo not recommend.

6) Is risk monitoring adequate to identify progression of the disease before the subject experience severe consequences?
   ☐Not applicable.
   ☐Yes, consider placebo
   ☐No, placebo not recommend.
7) Are there clearly defined stopping rules to withdraw the subject before the advent of severe disease progression?
   ☐Yes, consider placebo
   ☐No, placebo not recommend.
8) If the risk of placebo is an acute emergency, are rescue medication and emergency treatment available?
   ☐Not applicable.
   ☐Yes, consider placebo
   ☐No, placebo not recommend.
9) If the risk of placebo is the persistence of distressing symptoms, is concurrent medication to control them allowed?
   ☐Not applicable.
   ☐Yes, consider placebo
   ☐No, placebo not recommend.
10) If the risk of placebo is severely physical discomfort or pain, is there rescue medication?
   ☐Not applicable.
   ☐Yes, consider placebo
   ☐No, placebo not recommend.

IV. Risk disclosure in the consent form

1) Are the risks of getting placebo instead of active treatment fully disclosed?
   ☐Yes, consider placebo.
2) Are the risks of the test drug disclosed?
   ☐Yes, consider placebo.
2) Are the advantages of alternative treatments explained?
   ☐Yes, consider placebo.

Conclusions :

1. The use of placebo is ethically acceptable because:
   ☐Subjects are not exposed to severe or permanent harm by the use of placebo.
   ☐Subjects under placebo will benefit from the overall treatment of the disease.
   ☐Risks of the use of placebo are minimized.
   ☐Risks are adquately disclosed in the consent form.

2. The use of placebo in this study could be reconsidered if the following conditions are met:
……..…
……..…
3. The use of placebo in this study is ethically unacceptable because:
   ☐Subjects are exposed to severe or permanent harm by the use of placebo instead of active treatment.
   ☐Due to the nature of the disease, the risks of placebo can not be minimized.

ANNEXURE: 10 **AF/IEC/10/08/V7.1**

Guidance of Protocol Submission

The IEC is currently following the V7.1 dated 30 September 2017 of the Standard Operating Procedures (SOPs), which are individual activity based and are 24 in number.
The SOPs are available on the institutional LAN and the institute website.

The templates and forms are available on the Institute LAN for submission to the Ethics Committee

I. Prior to approval of a research study:

Submission of a New Study Proposal

- The study proposals will be circulated after receiving at IEC office to the internal members. They will provide feedback (comments and suggestions) to the PIs within 2 weeks.
- The PIs will make the corrections within a week and submit the required 12 number of copies to the IEC secretariat.
- The secretariat will send the copies at least 8 days in advance of the full board meeting to the external members.
- The protocol will be reviewed at the IEC meeting.
- An investigator is expected to be present at the time of full board meeting and will be invited (telephonically) to the IEC meeting to discuss issues related to the study proposal.
- After the full board, the approval letter will be given within 15 days.
- An investigator is expected to submit reply to the letter of recommendations/ queries sent by the IEC within 90 days of date of receipt of the letter. In the absence of any response, the protocol will be declared closed for the IEC office records.

II. Once approval for a study is granted

- An approval will be granted for usually one year study period.
- It is the responsibility of the principal investigator that for studies which will continue for more than a year, a continuing review report needs to be submitted (within 2 month of the due date i.e. 10 months from the date of approval)
- PI is responsible to submit continuing review report for the studies which will continue for more than a year (within 2 month of the due date i.e. 10 months from the date of approval)
- Submission of Study Related Documents for IEC review
- Study related documents (protocol amendments, SAE reports, status reports, study completion reports, protocol deviations/ violations) will be accepted during the office hours specified above. Only one set of the above stated study related documents need to be submitted for the IEC review as per the format.

  No changes in the protocol, case record form and /or Informed Consent Document shall be initiated without prior written approval from the committee, except when necessary to eliminate immediate hazards to the research participants.

  A covering letter should be submitted and the template for it is available on the LAN.

III. <u>Once a study is over</u>

Submission of Study Completion Report

- For studies which are completed within the IEC approval period, a study completion report as per the format should be submitted to the IEC, by the investigator.
- The study completion report is expected for review within 2 months of completion of the study at the site. A brief study report containing data analysis from all centres should be submitted once available from the sponsor.

IV In case a study is not initiated or terminated:

The same should be communicated to the IEC stating reasons for the same. The report of premature termination of the study should be given as per format.

ANNEXURE:11 **AF/IEC/11/08/V7.1**

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:

1. Trial Protocol (including protocol amendments), dated Version no (s).. _
2. Patient Infoffilation Sheet and Informed Consent Form (including updates if any) in English andlor vernacular language.
3. Investigator's Brochure, dated , Version no. _ dated
4. Proposed methods for patient accrual including advertisement (s) etc. proposed to be used for the purpose
5. Principal Investigator's current CV.
6. Insurance Policy / Compensation for participation and for serious adverse events occurring during the study participation.
7. Investigator's Agreement with the Sponsor.
8. Investigator's Undertaking (Appendix VII).

The following members of the ethics committee were present at the meeting held on (date, time, place).
Chairman of the Ethics Committee
Member secretary of the Ethics Committee
Name of the Each members with designation

The final decision on the protocol as under:

i) Approved [We approve the trial to be conducted in its present form] ☐
ii) Minor modification for expedited review ☐
iii) Major modification for full board review ☐
iv) Disapproved ☐

The Institutional Ethics Committee / Independent Ethics Conunittee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the fmal report. You are requested to submit the continuing letter at least 2 months before the end of -approval period.
Yours sincerely,

Chairman/Member Secretary, Ethics Committee.