ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BATHINDA
JODHPUR ROMANA, MANDI DABWALI ROAD, BATHINDA,
PUNJAB-151001

ਅਖਿਲ ਭਰਤੀਯ ਆਯੁਰਵਿਗਿਆਨ ਸੰਸਥਾਨ, ਬਠਿੰਡਾ अखिल भारतीय चिकित्सा विज्ञान संस्थान, बठिंडा

RESEARCH CELL

ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BATHINDA

INFORMATION AND GUIDELINES FOR RESEARCH PROPOSALS

Research Cell
ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BATHINDA-151001

researchcell@aiimsbathinda.in

INFORMATION AND GUIDELINES

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AIIMS BATHINDA: RESEARCH CELL
INFORMATION AND GUIDELINES

1. Background:

The Executive Director, AIIMS BATHINDA has constituted Research Cell (AIIMS BATHINDA-RAC) withthe prime objective of facilitating and monitoring funded/ non funded clinical, biomedical and epidemiological research being conducted by various departments of AIIMS BATHINDA.

2. Terms of Reference:

Following are the specific Terms of Reference of the Research Cell:

- To critically assess funded research projects prepared by departments of AIIMS BATHINDA and associated hospitals in various disciplines (bio-medical, clinical, epidemiological, behavioral and social)
- To forward and recommend funded research projects based on merit and strength of the protocol to the Institutional Ethics Committee (IEC) for consideration from ethical point-of-view
- To build capacity of various departments by orientation of their faculty and resident doctors and other research staff on research design, methodology, data analysis and scientific documentation for publication in peer-reviewed journals
- To facilitate implementation of projects awarded to AIIMS BATHINDA and associated hospitals and review their progress
- To build networks, alliances and partnerships with research organizations and academic institutions for multi-centric projects

AIIMS BATHINDA-RAC will meet at least once every three months or as and when required. The expenditure for the functioning of AIIMS BATHINDA-RC will be regulated at par and in accordance with the guidelines issued by ICMR for research related meetings.

3. Scope:

AIIMS BATHINDA-RAC will review and recommend all funded research proposals including those involving human participants for support and consideration by AIIMS BATHINDA IEC. The goals of research, however important, should never be permitted to override the health and well being of the research subjects. AIIMS BATHINDA-RAC will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures.

4. Quorum requirements:

A minimum of 5 members are required to compose a quorum ordinarily. All decisions should be taken in meetings and not by circulation of project proposals except in extraordinary circumstances where an expedited approval is indicated or the project has been earlier discussed in the RC.

5. Conduct of Meetings:

- RC Meetings would be presided over by the Chairperson. The meeting would be chaired by Co-chairperson when Chairperson is not available on scheduled date of the meeting.
- The Member Secretary/ Alternate Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the members of the RC and the PI/researchers
- All members of the RC should maintain absolute confidentiality of all discussions during the meeting.
- It is essential for all members of RC to declare in advance all forms of Conflicts of Interest (COI) in writing. COI include financial, relationship, patient care related, commercialization etc. All such COIs would be recorded and minuted.
- The RC would meet at least quarterly and more frequently if situation demands (depending on quantum of work).
- An effort shall be made to synchronize the RC and IEC meetings, so that the RC meeting will be held at least 2 weeks before the IEC meeting.

6. Guidelines for Research Proposals

Research Proposals will be submitted to the AIIMS BATHINDA-RAC giving details of the proposal generally under the following headings:

- Introduction,
- Review of literature,
- Rationale and Justification,
- Novelty
- Aim(s) & Objectives,
- Research Design, Methodology and Tools,
- Outcome measures,
- Statistical analysis
- Plans for publication of results

Information in model form (Form 1) should be provided by the Principal Investigator for examination by the RC as well as IEC.

For a thorough and complete review, all research proposals should be submitted with the following documents/information:

Four (4) consolidated copies of the following documents should be submitted and a consolidated PDF should be mailed to researchcell@aiimsbathinda.in . **The PDF file to be mailed should be renamed with the name of Principal Investigator and Title of the Project.**

- Form 1 (HOD)
- Form 2 (Checklist and PI details)
- Protocol
- Budget details- This should be itemized, and details of any financial benefits to the PI should be mentioned.
- PIS in English and Hindi (in the required format)
- Consent form in English and Hindi
- Brief CV of the investigators
- Undertaking (Form 3)

All Research Projects should be routed to the RC through the HODs. The HODs would give their comments and recommendation on a structured format (Form 1). HOD should comment on following issues:

- Whether routine patient care would be compromised as a result of this project?
- Whether functioning of the department would be affected?
- Would the project lead to improvement in the skills of manpower?

HOD would give his/her recommendation after looking into above mentioned aspects. In cases a proposal is not recommended by HOD, justification for the same would have to be mentioned specifically.

The proposals should be submitted to the Chair-person of AIIMS BATHINDA-RC and not to the Director, AIIMS BATHINDA. All incomplete proposals and those submitted in an inappropriate form will not be considered by the RC.

7. Review procedures:

- Vetting of Proposals would be done in RC meetings only, and NOT by circulation.
- Proposals would be circulated to members beforehand for its expeditious processing during the meeting.
- The date of meeting of RC will be intimated to all members of the RC and the PI/ Researcher.
- The meeting of the AIIMS BATHINDA-RC will be held on scheduled intervals as prescribed. Additional meetings may be held as and when the proposals are received for review.
- Researchers will be invited to make presentation on the proposal and/or for clarifications if need be.
- AIIMS BATHINDA-RC may call upon subject experts as independent consultants who may providespecial review of selected research protocols, if need be. They are required to give their specialized views and will generally not take part in the decision-making process. However, the chairperson may invite subject-experts to take part in the meeting

of the RC in specific circumstances

- Decisions will be taken by consensus after discussions
- The decisions shall be minuted and circulated to all members, after obtaining Chairman's approval.
- Decision regarding a proposal would ordinarily be communicated to PI within 7 days of finalization of the minutes of the RC meeting.

8. Elements of Review

The proposals will be objectively examined in depth in a transparent and unbiased manner and assessed on the following parameters:

- Strength of Scientific design of the study.
- Relevance and potential benefits of the study
- Novelty and feasibility of the study
- Competence of investigators, research and supporting staff
- Facilities and infrastructure of study sites
- Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria
- Examination of predictable risks/harms and management of research related injuries, adverse events and compensation provisions.
- Patient information sheet and informed consent form in local language.(Hindi and Punjabi)
- Protection of privacy and confidentiality.
- Plans for data analysis and reporting
- Budgetary provision- especially the institutional overheads and compensation costs
- Whether the investigator(s) are receiving any pecuniary benefits and they have sought administrative approval for the same.

9. Decision-making

- Members will discuss the various issues before arriving at a consensus decision.
- A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
- Decisions will be made only in meetings where quorum is complete.
- Only members can make the decision. The expert consultants will only offer their opinions.
- Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
- In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
- Modified proposals may be reviewed by an expedited review through identified members.

The decision of the RC will be communicated by the Member Secretary in writing to the PI. Suggestions for modifications, if any, will be sent to the PI in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting. In case a proposal has been rejected, RC will also inform the reasons for rejection to the Principal Investigater.

10. Expedited Review

In case the RC returns the proposal for major revision, the revised protocol would also have to be submitted in 4 copies for re-examination by the RC. However, for minor revisions, after checking that the appropriate corrections have been made, the member secretary may issue the approval.

Expedited review may be taken up in cases of nationally relevant proposals requiring urgent review. Such reviews will be carried out by identified members convened by the Chairman to expedite decision making. The nature of the applications, amendments, and other considerations that will be eligible for expedited review will be specified and approved by RC.

11. Follow up procedures

- Progress reports on approved projects should be submitted annually for review.
- Any changes in protocol, adverse events, premature closure, staff joining or leaving should also be intimated to the RC on an as and when basis.
- Final report should be submitted at the end of the study.
- Protocol deviation, if any, should be informed with adequate justifications. Any amendment to the protocol should be resubmitted for renewed approval
- Any new information related to the study should be communicated.
- Premature termination of study should be notified with reasons along with summary of the data obtained so far.
- Change of investigators / sites should be informed to the RC.

12. Record keeping and Archiving

The RC will compile following information and documents

- Copy of all study protocols with enclosed documents, progress reports and final reports
- Minutes of all meetings duly signed by the Chairperson.
- Copy of all correspondence with members, researchers and other regulatory bodies.
- Final report of the approved projects.
- Scientific Publications of all departments of AIIMS BATHINDA.
- Annual Report on **Funded** Research Work carried out at AIIMS BATHINDA and material for inclusion in Annual Report of AIIMS BATHINDA and Annual Report of the Ministry of Health & FW
- All documents should be archived for seven (7) years from the closure of the project.

ANNEXURE 1

AIIMS BATHINDA

COMPOSITION OF RESEARCH CELL COMMITTEE

S.No.	Name	Designation	Role
1	Prof. (Dr) Lajya Devi Goyal	Professor cum HOD Obs & Gynae	**Dean Research** Chairperson
2	Prof. Dr Anuradha Raj	Professor cum HOD Ophthalmology	**Associate Dean** Member Secretary
3	Dr. M. Altaf Mir	Associate Professor	Alt. Member Secretary
4	Dr. Soumya Swaroop Sahoo	Associate Professor	Alt. Member Secretary
5	Dr. Mintu Pal	Associate Professor	Member
6	Dr Vaibhav Saini	Additional Professor	Member
7	Dr. Rakesh Kakkar	Professor cum HOD CFM	Member
8	Dr. Gurvinder Pal	Professor cum HOD Psychiatry	Member
9	Dr. Ajay Kumar	Additional Professor	Member
10	Dr. Mayank Gupta	Associate Professor	Member
11	Dr. Mahendra Pratap Singh	Additional Professor	Member
12	Dr. Gitanjali	Professor cum HOD Biochemistry	Member
13	Dr. Paramdeep Singh.	Additional Professor	Member
14	Prof (Dr.) Kamlesh K Sharma	Professor cum Principal Institute of Nursing Education and Research (INER)	Member
15	Dr. Sivanantham Krishnamoorthi	Associate Professor	Member

Annexure 2: PARTICIPANT INFORMATION SHEET (PIS)

The project must be accompanied by the Participant Information Sheet addressed to the patient or participant or parent/guardian, in case of minor. While formulating the participant information sheet, investigator must provide the subjects with the following information in English and Hindi or punjabi language, in a narrative form, directed to Participant covering all the points given on the website, which can be understood by them:

i) Title of the Study/Project

ii) Aims and methods of the research.

iii) Expected duration of the subject participation.

iv) The benefits to be expected from the research to the subject or to others.

v) Any risk to the subject associated with the study.

vi) Provision of free treatment for research related injury.

vii) Compensation of subjects for disability or death resulting from such injury.

viii) Maintenance of confidentiality of records.

ix) Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.

x) Amount of blood sample in quantity, in Tea Spoon Full, to be taken should be mentioned.

xi) Costs and source of investigations, disposables, implants and drugs / contrast media must be mentioned.

xii) Telephone number/contact number of Principal Investigator and Co investigator at the top of each page.

xiii) In case of drug trials: a) The chemical name of the drug, date of its manufacturing and batch number must be mentioned b) Initial Bio equivalent study of the drug / references should be provided.

xiv) Statement that there is a possibility of failure of Investigational Product (IP) to provide intended therapeutic effect

xv) Statement that in case of placebo-controlled trials, the placebo administered to the subjects shall not have any therapeutic effect

xvi) Plans for publication including photographs

PARTICIPANT INFORMED CONSENT FORM (PICF)
(English)

Participant identification number for this trial: _____

Title of project:

Name of Principal Investigator: **Tel.No(s):**
Name of the Patient: _____ Age/Gender: _____

The contents of the information sheet dated_____that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from AIIMS, Bathinda, Punjab. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

---------- Date: _____
(Signatures / Left Thumb Impression) Place: _____

Name of the Participant: _____
Son / Daughter / Spouse of: _____
Complete postal address: _____

This is to certify that the above consent has been obtained in my presence.

Signatures of the Principal Investigator Date:
Place:

1) Witness – 1

Signatures
Name:

Address:

2) Witness – 2

Signatures
Name:

Address:

आंशिक सूचित सहमति फॉर्म (PICF)

इस परीक्षण के लिए प्रतिभागी की पहचान संख्या: _____
परियोजना का शीर्षक:

प्रधान अन्वेषक का नाम:

Tel.No (s):

रोगी का नाम: _____ आयु / लिंग: _____

जानकारी पत्र की सामग्री दिनांकित_____ को प्रदान की गई थी जिसे मेरे द्वारा सावधानीपूर्वक पढ़ा गया / मुझे विस्तार से समझाया गया, जिस भाषा में मैं समझता हूं, और मैं पूरी तरह से सामग्री को समझ गया हूं।मैं पुष्टि करता हूं कि मुझे सवाल पूछने का अवसर मिला है।
अध्ययन की प्रकृति और उद्देश्य और इसके संभावित जोखिम / लाभ और अध्ययन की अपेक्षित अवधि, और अध्ययन के अन्य प्रासंगिक विवरण मुझे विस्तार से बताए गए हैं।मैं समझता हूं कि मेरी भागीदारी स्वैच्छिक है और मैं बिना किसी कारण के किसी भी समय वापस लेने के लिए स्वतंत्र हूं, बिना मेरी चिकित्सा देखभाल या कानूनी अधिकार प्रभावित हुए बिना।
मैं समझता हूं कि इस शोध में मेरी भागीदारी और मेरे किसी भी मेडिकल नोट के अनुभागों के बारे में एकत्रित जानकारी को एम्स, बठिंडा, पंजाब के जिम्मेदार व्यक्तियों द्वारा देखा जा सकता है।मैं इन व्यक्तियों को अपने रिकॉर्ड तक पहुंचने की अनुमति देता हूं।

मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूं।

---------- तारीख: _____
(हस्ताक्षर / बाएं अंगूठे का निशान) जगह: _____

प्रतिभागी का नाम: _____
पुत्र / पुत्री / पति / पत्नी: _____
पूरा डाक पता: _____

यह प्रमाणित करना है कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त हुई है।

प्रधान अन्वेषक दिनांक के हस्ताक्षर:
स्थान:

1) गवाह - 1

हस्ताक्षर
नाम

पता

2) गवाह - 2

हस्ताक्षर
नाम:

पता

Form 1

All India Institute of Medical Sciences, Bathinda

RESEARCH CELL

Form for Comments of Head of Department

To
Chairperson
Research Cell
AIIMS BATHINDA

Title of the Project:_____

Principal Investigator:_____

Date of submission by PI to HOD: _____

I have gone through the Protocol along with Annexures submitted by PI for consideration ofRC and have following comments to offer:

1	Whether routine patient care would be compromised as a result of this project?	Yes/ No /NA
2	Whether functioning of the department would be adversely affected?	Yes/ No /NA
3	Would the project lead to improvement in the skills of faculty/staff of the Department	Yes/ No /NA
4	Whether PI/Co-PI has adequate capacity to undertake the Project?	Yes/ No /NA
5	Whether facilities and/or equipment available in the Department would be made available to PI and his team?	Yes/ No /NA
6	Any other comment on the Project	

The Proposal is forwarded and

(a) Recommended for approval by RC/IEC
(b) Recommended subject to above comments
(c) Not-recommended due to following reasons:

Signature

(Name & Designation with seal

Date

Form 2: To be filled by the Principal Investigator (PI) for submission to Research Cell (RC)

Please fill the form completely. Incomplete forms are liable to rejection.

Reference No. (*To be entered by RC) -*

Proposal Title:

	Name, Designation & Qualifications	**Address Tel & Fax Nos. Email ID**	**Signature**
PI			
Co-PI / Collaborators 1.			
2.			
3.			
Please attach brief Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years).			

Tick appropriately

Sponsor Information: 1. Indian a) Government Central ☐ State ☐ Institutional ☐ b) Private ☐
2. International Government ☐ Private ☐ UN agencies ☐
3. Industry National Multinational
Name and Contact Address of Sponsor: ☐ ☐
Total Budget: A. Does the budget reflect a) Institutional overheads Y/N Please give details _____ B. Any payments / benefits to the investigator's Y/N If Yes, please give details_____

1.Type of Study: Epidemiological ☐ Basic Sciences ☐ Animal Studies ☐

Clinical: Single center ☐ Multicentric ☐ Behavioral ☐

Faculty driven Student-driven ☐ Specify otherwise ☐

2. Status of Review: New Revised

3. Clinical Trials: Drug /Vaccines/Device/Herbal Remedies:

Does the study involve use of?

Drug ☐ Devices ☐ Vaccines ☐

Indian Systems of Medicine/ Alternate System of Medicine ☐ Any other ☐ NA ☐

i. Is it approved and marketed

In India ☐ UK & Europe ☐ USA ☐

Other countries, specify

iii. Does it involve a change in use, dosage, route of administration?	Yes	No
If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained?	Yes	No
If yes, Date of permission:		
iv. Is it an Investigational New Drug?	Yes	No
If yes, IND No:		
a). Investigator's Brochure submitted	Yes	No
b). *In vitro* studies data	Yes	No
c). Preclinical Studies done	Yes	No

d). Clinical Study is: Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐

e). Are you aware if this study/similar study is being done elsewhere?	Yes	No
If Yes, attach details		

i. **Brief description of the proposal** – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Attach sheet with maximum 500 words):

5. Subject selection:

i.	Number of Subjects :		
ii.	Duration of study:		
iii.	Will subjects from both sexes be recruited	Yes	No
iv.	Inclusion / exclusion criteria given	Yes ☐	No ☐

v. Type of subjects Volunteers ☐ Patients ☐

Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation

vi. Vulnerable subjects (Tick)

Pregnant women ☐ Children ☐ Fetus ☐ Handicapped ☐

Elderly ☐ Terminally ill ☐ Seriously ill ☐ Mentally Challenged ☐

Economically & Socially Backward ☐ any other (specify)

6. Privacy and confidentiality

i. Study involves - Direct Identifiers ☐
Indirect Identifiers/coded ☐
Completely anonymized/ delinked ☐

ii. Confidential handling of data by staff	Yes	No
7. Use of biological/ hazardous materials i. Use of fetal tissue or abortus	Yes	No
iii. Use of organs or body fluids	Yes	No
iii. Use of recombinant/gene therapy **If yes,** has Department of Biotechnology (DBT) approval for rDNA products been obtained?	Yes Yes	No No
iv. Use of pre-existing/stored/left over samples	Yes	No
v. Collection for banking/future research	Yes	No
vi. Use of ionising radiation/radioisotopes **If yes,** has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes Yes	No No
vii. Use of Infectious/biohazardous specimens	Yes	No
viii. Proper disposal of material	Yes	No
ix. Will any sample collected from the patients be sent abroad? **If Yes, justify with details of collaborators**	Yes	No
a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	Yes	No

b) Sample will be sent abroad because (Tick appropriate box): If so, reasons…

Facility not available in India

Facility in India inaccessible

Facility available but not being accessed.

8. Consent: *Written Oral Audio-visual

Consent from LAR

For children<7 yrs parental/LAR consent

Verbal assent from minor (7-12 yrs) along with parental consent
Written Assent from Minor (13-18 yrs) along with parental consent

Consent form: (tick the included elements)

Understandable language ☐ Alternatives to participation ☐

Statement that study involves research ☐ Confidentiality of records ☐

Sponsor of study	Contact information
Purpose and procedures	Statement that consent is voluntary
Risks & Discomforts	Right to withdraw
Benefits	Consent for future use of biological material
Compensation for participation	Benefits if any on future commercialization
Compensation for study related injury	
*If written consent is not obtained, give reasons:	

ii. Who will obtain consent?	PI/Co-PI	Nurse/Counsellor
	Research staff	Any other

9. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so, kindly attach a copy)	Yes	No

10. Risks & Benefits: i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?	Yes	No
ii. Is there physical / social / psychological risk / discomfort? **If Yes,** Less than Minimal risk ☐ Minimal Risk ☐ Minor increase over minimal risk or Low risk ☐ More than minor increase or High risk ☐	Yes	No
iii.Is there a benefit a) to the subject? Direct ☐ Indirect ☐ b) Benefit to society ☐		
11. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)	Yes	No
ii. Is there a plan for reporting of adverse events? **If Yes,** reporting is done to: Sponsor ☐ Ethics Committee ☐ DSMB ☐	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No
vi. Are there plans for storage and maintenance of all trial databases? **If Yes,** for how long?	Yes	No
12. Is there compensation for participation? **If Yes,** Monetary ☐ In kind ☐ Specify amount and type:	Yes	No
13. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator ☐ by insurance company ☐ by any other ☐	Yes	No
14. Do you have conflict of interest? (financial/nonfinancial) **If Yes, specify:** **In case the investigator(s) are receiving any payment or direct benefit due to the project, it may be considered a conflict of interest and should be detailed here. NOTE: It shall be the responsibility of the investigator(s) to take Appropriate administrative permissions for the pecuniary benefits *a priori.***	Yes Noted	No

Checklist for attached documents: 4 consolidated copies of the following

Form 1, Form 2, Form 3	☐
Project proposal	☐
Patient information sheet in English and Hindi	☐
Informed Consent form in English and Hindi	☐
Investigator's brochure for recruiting subjects	☐
Curriculum Vitae of Investigators	☐
Brief description of proposal	☐
Copy of clinical trial protocol and/or questionnaire	☐

Place:
Date:

Signature & Designation of PI/Co-PI/Collaborator

Form-3

UNDERTAKING BY THE INVESTIGATOR

1. Full name, address and title of the Principal investigator (or investigator (S) when there is no principal investigator)
2. Protocol Title and study number (if any) of the clinical trial to be conducted by the investigator
3. Commitments:

A. 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

B. 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 Funding agency/Sponsor and prior review and documented approval) and favorable opinion from the RC and Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when changers involved are any logistical or administrative in nature.

C. I agree to personally conduct and / or supervise the clinical trial at my site.

D. I agree to inform all Subjects; 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 OCP guidelines are met.

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

F. I have read and understood the information in the investigator's brochure, including the potential risks and side effects of the intervention.

G. I agree to maintain adequate and accurate records and t make those records available for adult / inspection by the Sponsor, Ethics Committee, Licensing Authority or Their authorized representatives, 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.

H. I 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 their obligations in meeting their commitments in the trials

I. I agree to inform all unexpected serious adverse events to the Funding agency/Sponsor as well as the Ethics Committee within 24 hours of their occurrence.

J. I agree to promptly report the ethics Committee all changes in the clinical trial activates and all unanticipated problems involving risks to human Subjects or others

K. I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.

L. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical investigators participating in clinical trials.

Signature of PI with date