Institutional Ethics Committee

Of

Madras Christian College

(IEC – MCC)

Standard Operating Procedure
(SOP)

January 2023

1. Introduction:

Institutional Ethics Committee, Madras Christian College (IEC-MCC) has been constituted by the Principal, Madras Christian College, to facilitate research involving human subjects following due guidelines set bythe ICMR Ethical guidelines. This standard operating procedure document will define the role, operation and management of the Committee.

2. Objective:

The objective of this SOP is to put in place an effective and consistent ethical review mechanism for health, biomedical and research involving human subjects for all proposals submitted by thefaculty, research scholars and students of Madras Christian College as prescribed by the National Ethical guidelines for biomedical and health research on human participants of ICMR (2017).

3. Role and responsibilities of the committee:

IEC-MCC will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, privacy, rights, safety and well-being of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and well-being of the research subjects/participants. The IEC- MCC will take care that all the cardinal principles of research ethics viz Autonomy, Beneficence, Non - malfeasance and Justice are taken care of in planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It 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, such as annual reports, final reports and site visits etc. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws. The mandate of the IEC-MCC will be to review all research projects involving human subjects including human biological materials and human biological data to be conducted at the Institute, irrespective of the funding agency.

4. Composition of the committee:

IEC-MCC should be multidisciplinary and multi-sectorial in composition. Independence and competence are the two hallmarks of an IEC-MCC. The number of persons in an ethical committee

will be around 8-14 members.

The Chairperson of the Committee should be non-affiliated from the Institution with a legal backgroundand not the head of the Institute to maintain the independence of the Committee. The Member Secretary will be a faculty member from the Institution to conduct the business of the Committee. Other members will be a mix of medical / non-medical, scientific and non-scientific persons including lay public to reflect different viewpoints.

The composition will be as follows:

Chairperson
1-2 basic medical scientists.
1-2 clinicians from various Institutes
One legal expert
One social scientist / representative of non-governmental voluntary agency
One philosopher / theologian
One lay person from the community
Member-Secretary

There should be adequate representation of age, gender, community, etc. in the Committee to safeguard the interests and welfare of all sections of the community / society. Members should be aware of local, social and cultural norms, as this is the most important social control mechanism. If required, subject experts could be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist, should be included. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Committee.

4.1 Authority constituting the Institutional Ethics Committee

The members will be appointed by the Principal & Secretary of Madras Christian College based on their competencies and integrity and could be drawn from any public or private Institute from anywhere in the country.

4.2 Membership requirement:

The Principal of Madras Christian College will constitute the IEC – MCC according to the National Ethical guidelines for biomedical and health research on human participants of ICMR (2017).

The membership requirements are

i. The duration of appointment will be initially for a period of 2 years

ii. At the end of 2 years, the committee is to be reconstituted and 50% of the members will be replaced by a defined procedure.

iii. A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.

iv. A member can tender resignation from the committee with proper reasons to do so.

v. All members should maintain absolute confidentiality of all discussions during the meeting.

vi. Conflict of interest should be declared by members of the IEC-MCC

4.3 Quorum:

A minimum of 5 members and the Chairperson are required to make up a quorum. This quorum must include at least one non-scientific member that may either be a lawyer, philosopher or a lay person from the community.

4.4 Offices

The Chairperson will conduct all meetings of the Institutional Ethics Committee. In case of the absence of the Chairperson, a deputy chairperson or an alternate chairperson will be elected from the members by the members present to conduct the meeting.

The Member secretary will be responsible to schedule the meeting in consultation with the Chairperson and members of IEC-MCC. The Office of the member secretary will receive all the applications and maintain record of the activities of IEC. The Member Secretary will prepare the minutes of the meetings and have it approved by the Chairperson before communicating to the researchers with the approval of the appropriate authority. The office of the Institutional Ethics Committee – MCC will function through the office of the Deanery of Research and Development in Madras Christian College.

4.5 Independent Consultants

IEC-MCC may call upon subject experts as independent consultants who may provide special review

of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities; patient groups or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities. They are required to give their specialized views which can be instrumental in the decision-making process made by the members of the IEC-MCC.

4.6 Resignation, Removal and Reconstitution

The members who have resigned may be replaced at the discretion of the appointing authority for the same i.e., The Principal, Madras Christian College. IEC-MCC members who decide to resign must provide to the Principal, Madras Christian College and Chairman, IEC-MCC a written notification of their proposed resignation date atleast 30 calendar days prior to the next scheduled meeting. In case of resignation, the Principal, Madras Christian College would appoint a new member, falling in the same category of membership, that is a Medical Scientist with a Medical Scientist. Recommendations may be sought from the resigning member. Appointment may be made in consultation with the Member Secretary and/or Chairperson.

A member may be relieved or terminated of their membership in case of

- Conduct unbecoming for a member of the Ethics Committee
- Inability to participate in the meetings on any grounds
- Failure to attend more than 3 meetings of IEC.
- Relocation to another city or any such matter

The membership shall be reviewed by the IEC-MCC if the member is a regular defaulter. If deemed necessary, the IEC may decide to terminate the membership and recommendation can be made to the Principal, Madras Christian College, by the Chairman IEC-MCC for necessary action.

4.7 Training of Members:

i. All relevant new guidelines should be brought to the attention of the members.

ii. Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area. Certificate of participation should be kept in record.

4.8 Conflict of Interest

It has been recognized that the potential for conflict of interest will always exist but has faith in the IEC-MCC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects. When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the proposal review or approval except to provide information requested by the Committee.

If an applicant submitting a protocol believes that an IEC-MCC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol. The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IEC-MCC member(s) in question. The committee may elect to investigate the applicant's claim of the potential conflict.

Conflict of interest may arise through any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitiveadvantage.
- A member's personal biases may interfere with his or her impartial judgment.

5. Application Procedure

i. All proposals should be submitted in the prescribed application form (see Annexure).

ii. All relevant documents should be enclosed with application form (see Annexure).

iii. A soft copy of the proposal along with the application in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators must be sent to the Member Secretary.

iv. The date of meeting will be intimated to the researcher to be present for clarification.

v. The decision will be communicated in writing. If revision is to be made, the revised document should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

5.1 Documentation:

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

documents:

i. Name of the applicant with designation

ii. Name of the Institution / Hospital / Field area where research will be conducted.

iii. Letter approved and forwarded by the Head of the Institution /Head of the Department.

iv. Protocol of the proposed research

v. List of Ethical issues in the study and plans to address these issues.

vi. Relevant enclosures like proforma, case report forms, questionnaires, follow - up cards, etc.

vii. Informed consent process, including patient information sheet and informed consent form in local language(s).

viii. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data fromother centres within the country / countries, if available.

ix. Curriculum vitae of all the investigators with relevant publications in last five years.

x. Any regulatory clearances required.

xi. Source of funding and financial requirements for the project.

xii. Other financial issues including those related to insurance

xiii. An agreement to report all Serious Adverse Events (SAEs)

xiv. Statement of Conflict of interests, if any

xv. An agreement to comply with all national and international guidelines

xvi. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable;

xvii. All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.

xviii. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.

xix. Any other information relevant to the study

5.2 Review Procedure

i. The meeting of the IEC-MCC should be held at scheduled intervals.

ii. The proposals will be sent to members at least 2 weeks in advance.

iii. Decisions will be taken by consensus after discussions, and whenever needed voting will be done.

iv. Researchers will be invited to offer clarifications if need be.

v. Independent Consultants/Experts will be invited to offer their opinion on specific research proposals if needed.

vi. The decisions will be minuted and Chairperson's approval taken in writing.

5.3 Element of Review

i. Scientific design and conduct of the study

ii. Approval of appropriate scientific review committees

iii. Examination of predictable risks/harms

iv. Examination of potential benefits

v. Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details

vi. Management of research related injuries, adverse events

vii. Compensation provisions

viii. Justification for placebo in control arm, if any

ix. Availability of products after the study, if applicable

x. Patient information sheet and informed consent form in local language

xi. Protection of privacy and confidentiality

xii. Involvement of the community, wherever necessary

xiii. Plans for data analysis and reporting

xiv. Adherence to all regulatory requirements and applicable guidelines

xv. Competence of investigators, research and supporting staff

xvi. Facilities and infrastructure of study sites

xvii. Criteria for withdrawal of patients, suspending or terminating the study

5.4 Expedited Review

All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of identified members convened by the Chairperson to expedite decision making. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review. The nature of the applications, amendments, and other considerations that will be eligible for expedited review should be specified. To expedite review a sub- committee consisting of the member secretary, a non-scientific and a scientific member maybe constituted under the Chairperson / Deputy Chairperson to review the proposal and is to be approved by the Chairperson.

5.5 Decision-making

i. Members will discuss the various issues before arriving at a consensus decision.

ii. 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.

iii. Decisions will be made only in meetings where quorum is complete.

iv. Only members can make the decision. The expert consultants will offer their opinions.

v. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.

vi. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.

vii. Modified proposals may be reviewed by an expedited review through identified members.

viii. Procedures for appeal by the researchers should be clearly defined.

5.6 Communicating the decision

i. Decision will be communicated by the Member Secretary in writing.

ii. Suggestions for modifications, if any, should be sent by IEC-MCC.

iii. Reasons for rejection should be informed to the researchers.

iv. The schedule / plan of ongoing review by the IEC-MCC should be communicated to the PI.

5.7 Follow up procedures

i. Reports should be submitted annually for review.

ii. Final report should be submitted at the end of study.

iii. Protocol deviation, if any, should be informed with adequate justifications.

iv. Any amendment to the protocol should be resubmitted for renewed approval.

v. Any new information related to the study should be communicated.

vi. Premature termination of study should be notified with reasons along with summary of thedata obtained so far.

vii. Change of investigators / sites should be informed.

5.8 Record keeping and Archiving

i. Curriculum Vitae (CV) of all members of IEC.

ii. Copy of all study protocols with enclosed documents, progress reports, and Serious AdverseEvents.

iii. Minutes of all meetings duly signed by the Chairperson.

iv. Copy of all existing relevant national and international guidelines on research ethics and lawsalong with amendments.

v. Copy of all correspondence with members, researchers and other regulatory bodies.

6. Policy to protect vulnerable population and compensation:

A vulnerable category of subjects includes children, prisoners, pregnant women, handicapped or mentally disabled persons, refugees, displaced persons and economically or educationally

disadvantaged persons, who are likely to be vulnerable to coercion or undue influence. Projects that involve vulnerable population and special groups should be subjected to full review by all the members.

Compensation: If a participant volunteers to involve him/her in the study. If the study requires more than one hour of his time, he/she has to be compensated with suitable compensation. No study should involve financial burden to the participant. All financial expenditure should be included in the project proposal.

Annexures

FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY INSTITUTIONAL ETHICS COMMITTEE OF MADRAS CHRISTIAN COLLEGE (IEC-MCC)

IEC-MCC will be operating following the Standard operating procedure (SOP) uploaded in College website. The Institutional Ethics Committee will review the following three types of communications;

1. Fresh project submission and reply to comments from IEC
2. Amendments to ongoing projects
3. Progress report of approved projects

You are required to submit your research project through email and hard copy of the Research Project in original along with a Covering letter to the Member-Secretary, Institutional Ethics Committee - MCC at the office of the Deanery - Research & Development.
Email: iec@mcc.edu.in

- Hard copy will be used for record and soft copy will be used for all review process.
- All soft copies should be summited in PDF format only
- Check list of documents to be submitted for each application
    a) Institutional Ethical Committee application form (Form 1)
    b) Covering letter forwarded through Head of the Department
    c) Proposed Protocol for Research (Form 2)
    d) Proposed Protocol for Clinical Trials (Form 2)
    e) Participant Information Sheet (English & Regional Language) (Form 3)
    f) Participant Informed Consent Form (English & Regional Language) (Form 4)
    g) CV of all the Investigators (PI's and Co-PI's)
    h) Investigators brochure (infrastructure available)

i) Undertaking that the study will be done in accordance with ICMR guidelines (Form 5)

j) Letter of Undertaking from the Investigators as to who will bear the expenditure in case of injury related to study

k) In case of multi-centric study, IEC clearance of other centers must be provided

l) Investigator should provide dated undertaking what they will do with the leftover sample tissue (if applicable)

m) Other documents as applicable

The Principal Investigator must submit the protocol forwarded by Head of The Department. All submissions should be made in the prescribed Format of the **Institutional Ethics Committee** with signatures of all the investigators on the hard copy. All the pages must be numbered. No research project shall be / can be started unless an ethical clearance/approval is obtained. No retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor vetted by the Institutional Ethics Committee.

Form 1

Proforma to be submitted to the Institutional Ethics Committee

1. Title of the project:
2. Name of the investigators/co-investigators with designation & department:
3. Details of projects already with the investigators/co-investigators:
4. Sources of funding:
5. Objectives of the study:
6. Justification for the conduct of the study:
7. Methodology:
   (Details of the number of patients/ respondents, inclusion criteria, exclusion criteria, control(s), study design, dosages of drug, duration of treatment, investigations done, etc)
8. Permission from Drug Controller General of India (DCGI) if applicable
9. Costs involved (Appx. Budget In Rupees)
10. Ethical issues involved in the study: (for guidance please consult ICMR guidelines).
    (less than minimal risk / more than minimal risk to the study subjects)
11. Do you need exemption from obtaining Informed Consent from study subjects ?
    (If Yes, give justifications)
12. Whether Informed Consent forms in English and in local language are enclosed?
13. List of Documents attached
14. Conflict of interest for any other investigator(s) (if yes, please explain in brief)

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 Co- Investigators:

Signature of the Head of the Department

(Note: The proforma must be accompanied by consent forms in English and Regional Language. 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 RESEARCH / 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. Complete 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 and other departments and /or facilities participating in the study.

2. Table of Contents

A complete Table of Contents including a list of all Appendices will form a part of the protocol for clinical trials.

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
    i. 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.
4. 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

    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

d. Storage conditions for study substances

e. 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.

f. 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

Form III

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, the investigator must provide the subjects with the following information in English and the regional language in a simple layman's language, in a narrative form, directed to Participant /LAR, 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. Maintenance of confidentiality of records.

vii. Provision of free treatment for research related injury.

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

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. Self-certification should be given that translation to vernacular is accurate.

xv. Statement that there is a possibility of failure of IP to provide intended therapeutic effect

xvi. Statement that in case of placebo controlled trials, the placebo administered to the subjects shall not have any therapeutic effect

Form IV

INFORMED CONSENT FORM

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 any questions.

(ii) I understand 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 _____/_____/_____

Signature of the Investigator: _____

Study Investigator's Name:_____

Signature of the Witness_____ Date: _____/_____/_____

FORM V

UNDERTAKING BY THE INVESTIGATOR

1. Full name, address and title of the Principal Investigator
2. Name and address of the College, hospital or other facility where the trial will be conducted:
3. Education, training & experience that qualify the Investigator for the Study: (Attach details including Medical Council registration number in case of a clinical trial, and /or other statement(s) of qualification(s)
4. Name and address of laboratory facilities to be used in the study
5. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.
6. 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).
7. Protocol Title and study number (if any) of the clinical trial to be conducted by the Investigator.

   Commitments:

   (i) I have reviewed the 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 / favourable 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 study / clinical trial at my site.

(iv) I agree to inform all subjects/ respondents, that the study is 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 ICMR 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 guidelines.

(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 study.

(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.

(ix). 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 any changes in the study and all unanticipated problems involving risk to human subjects or others.

(x) I agree to inform all unexpected serious adverse events to the institution / sponsor as well as the Ethics Committee within seven days of their occurrence.

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

(xii) I agree to comply with all other requirement, guidelines and statutory obligations as applicable.

Signature of Investigator with date