Standard Operating Procedures

For

Institutional Ethics Committee

Mandya Institute of Medical Sciences,
Mandya-571401

Contents

I. Short Description of SOP.

The following may be called as "Standard Operating Procedures for the Institutional Ethics Committee (Human Studies) (IEC) of Mandya Institute of Medical Sciences, Mandya".

II. Adoption of SOP.

Mandya Institute of Medical Sciences, Mandya herein after referred to as "MIMS,Mandya" has adopted these written Standard Operating Procedures (SOP/SOPs) to ensure the protection of the rights and welfare of human participants in biomedical, experimental and behavioral research conducted at MIMS,Mandya.

III. Objectives of SOP.

The objective of this Standard Operating Procedures of the Institutional ethics committee (IEC) of Mandya Institute of Medical Sciences, Mandya is to maintain effective functioning of the IEC and to ensure quality and technical excellence and consistent ethical review of all the submitted health and biomedical research proposals and ongoing approved research studies involving human participants in accordance with the ICMR ethical guidelines for biomedical research on human participants.

IV. Authority for constituting the IEC.

The Director, MIMS, Mandya will appoint the Chairperson and all the committee members based on their competence, experience and integrity by request (Annexure-1). Members will confirm their acceptance to the Director by providing all the required information for membership (Annexure-2). The Chairperson will furnish any information or report to the Director, MIMS, Mandya when required.

V. Role and Responsibilities of IEC.

The IEC will review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of all actual and potential research participants before approving the research proposals. The goals of research, however important, should never be permitted to override the health and wellbeing of the human participants.

The IEC will ascertain whether all the cardinal principles of research ethics viz., *Autonomy, Beneficence, Non – maleficence, Respect for Free and Informed Consent, Respect*

for Human Dignity, Respect for Vulnerable Persons , Respect for Privacy and Confidentiality and Justice are taken care of in planning, conducting and reporting of the proposed research. For this purpose, it will look into the aspects of *protocol review, selection of participants, voluntary participation of potential participants, informed consent process, risk benefit ratio, distribution of burden and benefit, maintenance of privacy and confidentiality and provisions for appropriate compensations*.

IEC will review the proposals before the commencement of the study as well as review periodically until the completion of the study through appropriate well documented procedures. Such a review may be based on the periodic study progress reports furnished by the investigators and/or monitoring and internal audit reports furnished by the Sponsor and/or by visiting the study sites.

The mandate of the IEC shall be to review all research projects to be conducted in the Institution involving human beings directly or indirectly, irrespective of whether the research project is funded or non-funded, and if funded, then irrespective of the funding agency. In case IEC revokes its approval accorded to a trial protocol, it will record the reasons for doing so and at once communicate such a decision to the Investigator as well as to the Licensing Authority.

In case of serious adverse event or death occurring to the clinical trial participant, the IEC shall forward it's report on the serious adverse event or death, after due analysis, along with its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, whosoever had obtained permission form the Licensing Authority as defined under rule 21(b) for conducting the clinical trial, to DCGI/ Chairman of the Expert committee constituted by the Licensing authority under Appendix XII (gazette notification 30th January 2013) with a copy of the report to the Licensing Authority as per Schedule Y guidelines.

VI. Composition of IEC.

IEC will be a multidisciplinary and multi-sectorial body in composition and independent. The number of members of the Review Board may range from 7 to 15.

The chairperson/ Chairman of the IEC will be from outside the Institution to maintain the independence of the Committee. The Member Secretary will belong to the same Institution and will conduct the business of the Committee. Other members will be a mix of medical / non-medical, legal, scientific and nonscientific persons and may also include members of public to reflect the different points of view.

There will be adequate representation of age and gender in the Committee to safeguard the interest and welfare of all sections of the society. Member should be aware of local, social and cultural norms, as this is an important social control mechanism. IEC may invite subject experts to take their views, whenever it is needed.

The IEC of MIMS, Mandya will include

1. Chairperson/Chairman –from outside the institute
2. One / two persons from basic medical science area (One pharmacologist compulsorily)
3. One / two clinicians
4. One or more legal expert or retired judge
5. One or more social scientist / representative of non-governmental voluntary organization / agency
6. One or more philosopher/ ethicist/ theologian
7. One or more lay person (non-medical background) from the community
8. Member Secretary – from within the institute

A sub-board/ subcommittee of the main IEC may be formed by the chairman of IEC to review research proposals (Synopsis) of Post-Graduate students and ICMR STS Undergraduate/Post Graduate students similarly another subcommittee of the main IEC may be formed to review research proposals which necessitates expedite review as per ICMR guidelines.

VII. Requirements for IEC Membership

1. All members will serve for a period of 3 years on renewable basis. New members will be included in the IEC in such a way that there will be a mix of recently included members and members with some years of experience.
2. During the term, Director of the Institute in consultation with the Chairman can disqualify any member, if the contribution is not adequate and/or there is long period of non-availability of the members.
3. A member can tender resignation of his office of membership from the IEC to the Director through the Chairperson after serving one month advance notice.
4. Director of the Institute can replace the member of IEC as and when required.
5. Each member is required to sign the declaration and confidentiality agreement regarding IEC activities (Annexure -2)
6. Conflict of interest should be declared by members of the IEC prior to review meeting.

VIII. Quorum requirements

Minimum of 5 members are required to constitute the quorum for the meeting of which at least one member has to be from outside the institution, and one member will be a non-scientific member & one from opposite gender. All decisions will be taken in meetings and not by circulation of project proposals. Quorum will have 5 members with following representations:

(a) Basic medical scientists (preferably one pharmacologist).
(b) Clinician
(c) Legal expert
(d) Social scientist / representative of non-governmental voluntary agency / philosopher / ethicist / theologian or a similar person
(e) Lay person from the community.

IX. Conduct of IEC meetings

The Chairman will conduct all meetings of the IEC. In the absence of the Chairman, an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. The 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 Chairperson.

X. Independent consultants

The IEC 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 will be required to give their specialized views but should not take part in the decision making process which will be made by the members of the IEC.

XI. Application procedures

1. All research proposals should be submitted on any working day, the details of which are given under “Documentation”. The applicant may ask for copy of SOP from the IEC by paying fees of Rs 500, if the same has not been available on the institution website.
2. Application of the research proposal along with relevant documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators /

Research Scholars shall be guided to the Chairperson-IEC, MIMS, Mandya, through member secretary. Receipt of the application will be acknowledged by the IEC office.

3. Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of IEC meeting will be intimated to the PI. PI shall attend the meeting; make a brief presentation of the proposal and to clarify the points raised by the members.
4. The decision of the committee on the proposal will be communicated 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.
5. All research proposals/clinical trials funded/sponsored by Pharmaceutical companies/ Agencies/ Multinationals etc. will be charged an administrative fee/ processing fee of ***Rupees Twenty Five Thousand for fresh proposals*** ***and Rupees Twenty Five Thousand for annual follow-ups/renewal review proposals.***

   All non funded/ funded (funded by organizations like ICMR, UGC, DST Government of India, State Science & Technology Department, UNICEF, WHO, USAID, Non Profitable Organizations etc) research proposals by students & staff of MIMS, Mandya will be charged an administrative fee/ processing fee of ***Rupees One Thousand five hundred for fresh proposals.***

Waiver of these fees is permissible for Post Graduate Synopsis of RGUHS and Under Graduate Students of MIMS, Mandya for ICMR-STS projects. **Waiver of fees is at the discretion of Chairman-IEC, MIMS, Mandya.**

Fees is to be paid in the name of **IEC-MIMS, Mandya or INSTITUTIONAL ETHICS COMMITTEE, MIMS, Mandya** payable at Mandya by way of **DEMAND DRAFT** only

XII. Documentation

All Research proposals -hard copies along with soft copy (covering letter, proposals, Checklist etc in M S Word Format and certificates/insurance etc in PDF format on CD/DVD) along with the information and documents as specified in Annexures-3 and 4 shall be forwarded through the Head of the Department to IEC. **See also XIII. Review Procedures**. (Documents/SOP will be available on Institute's Website.

XIII. Review procedures

1. The meeting of the IEC will be held on periodic intervals, i.e. third and fourth Saturday of January, March, May, July, September, November unless otherwise specified by the member secretary. Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the work load.

2. The research proposals (4-hard copies with one softcopy) forwarded through Head of the Department to IEC before 5th of every month will be sent to Institutional Scientific Committee (ISC) / Scientific Review board of MIMS, Mandya for review of scientific design of the research proposals. After approval from ISC, the research proposals (8 copies to be submitted by PI with Soft copy on CD/DVD to IEC) will taken up for review in scheduled IEC meeting of the month if received, a minimum of 12 days prior to meeting date, else will be reviewed in subsequent IEC meeting. All research proposals unapproved by the ISC, shall be resubmitted by PI with necessary corrections/ amendment as specified by ISC (fresh 10-copies with amendments with Soft copy on CD/DVD) to IEC within the stipulated date as mentioned in the communication by IEC. IEC's member-secretary or secretariat will screen the proposals for their completeness and abiding ISC decisions. Proposals If found incomplete will be summarily rejected and need to apply again and will be considered as fresh proposals.

3. The IEC's member-secretary or secretariat will screen the approved research proposals by ISC of MIMS, Mandya and depending on the risk involved categorize them into three types, namely, *exemption from review, expedited review and full review* (as per ICMR's Ethical Guidelines for Biomedical Research on Human Participants-2006).

4. Researchers will be invited to offer clarifications if need be. The PI / Research Scholar will then present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the Co-PI will present the proposal.

5. Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed.

6. Decisions will be taken by consensus after discussion, and whenever needed voting will be done. Decision of chairperson will be final. The decisions will be minuted and Chairperson's approval taken in writing.

XIV. Aspects considered during review of research proposal by IEC

1. Approval by appropriate scientific review committees / Research committee / Institutional Scientific Committee of MIMS, Mandya (review of scientific design of the research Proposals).

2. Procedure for selection of subjects including inclusion / exclusion, withdrawal criteria and other issues like advertisement details.
3. Protection of privacy and confidentiality.
4. Involvement of the community, wherever necessary
5. Sample size (with justification)
6. Patient information sheet, informed consent form in English and in local languages.
7. Plans for data analysis and reporting.
8. Examination of potential benefits
9. Availability of products, benefits to subjects after the study is completed if applicable.
10. Examination of predictable risks/harms
11. Management of research related injuries, adverse events.
12. Compensation provisions.
13. Justification for placebo in control arm, if any
14. Competence of investigators, research and supporting staff.
15. Facilities and infrastructure of study sites.
16. Criteria for withdrawal of patients, suspension or premature termination of a study.
17. Adherence to all regulatory requirements and applicable guidelines.

XV. Decision-making

1. Members will discuss the various issues before arriving at a consensus decision. When consensus is not arrived at, the decision will be made by voting procedure.
2. 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.
3. Decision will be made only in meetings where quorum is complete.
4. Only the members can make the decisions. The expert consultants will only offer their opinions.
5. Decision may be to approve, reject or revise the proposals. Specific *suggestions for modifications and reasons for modifications and reasons for rejection* will be given.
6. *Modified proposals will be reviewed by an expedited review* through identified IEC members.
7. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified
8. Procedures for appeal by the researchers will be clearly defined.

XVI. Communicating the decision

1. Decision of the meeting on the proposals will be communicated by the Member Secretary/secretariat to the PI / Research Scholar within two weeks after the meeting at which the decision was taken in the specified ICMR format. All the approvals will be valid for one year or for the duration of the project whichever is less. Investigator has to get his or her project re- approved after one year, where required.
2. The communication letters shall be collected by the PI from IEC office.

XVII. Following up procedures for approved proposals by PI / Sponsor

1. IEC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.
2. Progress of all the research proposals will be followed at a regular interval of at least once a year. But in special situations, IEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research project.
3. Periodic status report of study should be submitted at prescribed intervals for review, along with information and documents as specified in Annexure- 7 based on the safety concerns and this prescribed interval shall be specified in the Letter of Communication of Decision to the PI from the IEC.
4. Following instances and events will require the follow-up review/ Renewed Approval:
   a. Any protocol amendment likely to affect rights, safety or well-being of research subject of conduct of study.
   b. Serious or unexpected ADR related to study or product, action taken by Investigator, Sponsor and Regulatory Authority.
   c. Any event or information that may affect the benefit/risk ratio of the study.
5. No Protocol deviation will be allowed.
6. Any new information related to the study should be communicated.
7. Premature termination of study shall be notified with reasons along with summary of the data obtained so far.
8. Change of investigators must be informed to the office of IEC within seven days.
9. Monitoring: Oversight mechanism will be in place to monitor the approved studies. Actual site visits can be made especially in the event of reporting of adverse events or violations of human rights and appropriate action will be taken when required and communicated to the applicant indicating modification/suspension/termination /continuation of the project. In case the IEC desires so, reports of monitoring done by the sponsor and the recommendations of the DSMB may also be sought.
10. Applicant – i.e PI must inform the completion of study (within 15 days) and must submit the result summary to IEC (within 90 days).

XVIII. Responsibilities of Sponsor/Investigator

Responsibilities of Sponsor

(i) The clinical trial Sponsor is responsible for implementing and maintaining quality assurance systems to ensure that the clinical trial is conducted and data generated, documented and reported in compliance with the protocol, Good Clinical Practice (GCP) Guidelines issued by the Central Drugs Standard Control Organization, Schedule Y/ Drugs and cosmetics act, Directorate General of Health Services guidelines, Government of India, ICMR ethical guidelines for biomedical research in human participants -2006, as well as with all applicable statutory provisions. Standard operating procedures should be documented to ensure compliance with GCP and applicable regulations.

(ii) Sponsors are required to submit a status report on the clinical trial to the Licensing Authority at the prescribed periodicity.

(iii) In case of studies prematurely discontinued for any reason including lack of commercial interest in pursuing the new drug application, a summary report should be submitted within 3 months. The summary report should provide a brief description of the study, the number of patients exposed to the drug, dose and duration of exposure, details of adverse drug reactions (Annexure 8), if any, and the reason for discontinuation of the study or non-pursuit of the new drug application;

(iv) Any report of serious adverse event /death occurring in clinical trial, after due analysis shall be forwarded by the sponsor to chairman of the ethics committee, DCGI and chairman of the expert committee constituted by the licensing authority as defined under Schedule Y (latest version at the time of Incident).

(v) In case of injury or death occurring to the clinical trial subject, the sponsor (whether a pharmaceutical company or an Institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall make payment for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the manner as prescribed in Schedule Y (latest version at the time of Incident).

(vi) The sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall submit details of compensation provided or paid for clinical trial related injury or death, to the Licensing Authority as prescribed in Schedule Y (latest version at the time of Incident).

Responsibilities of the Investigator(s)

(i) The Investigator(s) shall be responsible for the conduct of the trial according to the protocol and the GCP Guidelines and also for compliance as per the undertaking given in Appendix VII of schedule Y. Standard operating procedures are required to be documented by the investigators for the tasks performed by them. During and following a subject's participation in a trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events. Investigator(s) shall report all serious and unexpected adverse events to the Licensing Authority as defined in Schedule Y, the sponsor or his representative, whosoever had obtained permission form the licensing authority for conduct of the clinical trial, and the ethics committee that accorded approval to the study protocol, within the stipulated period of their occurrence as per Schedule Y. The report of the serious adverse event of death, after due analysis shall be forwarded by the investigator to Chairman of the ethics committee and DCGI/Chairman of the Expert Committee constituted by the Licensing authority under Appendix XII with a copy of the report to the Licensing Authority and the head of the institution where the trial has been conducted within the stipulated period of their occurrence as per Schedule Y(latest version at the time of Incident). The report of the serious adverse event /death, after due analysis shall be forwarded to the DCGI, Licensing Authority, Chairman of the Ethics Committee and the Head of the Institution where the trial has been conducted within the stipulated period of their occurrence as per Schedule Y(latest version at the time of Incident).

(ii) The investigator shall provide information to the clinical trial subject through informed consent process as provided in Schedule Y about the essential elements of the clinical trial and the subject's right to claim compensation in case of trial related injury or death. He shall also inform the subject or His/ Her nominee(s) of their rights to contact the sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial for the purpose of making claims in the case of trial related injury or death.

All the documents related to research proposals will be archived for a minimum period of 3 years by the PI/Researcher, following the completion / termination of the study.

XIX. Record keeping and archiving at the office of IEC

1. All the documents and communications of IEC will be dated, filed and archived in a secure place.
2. Only the member secretary or persons, who are authorized by the Chairman of IEC will have the access to the various documents.
3. All the documents related to research proposals will be archived for a minimum period of 3 years in the Institute, following the completion / termination of the study.
4. No document (except agenda) will be retained by any IEC member.
5. At the end of each meeting, every member must return the research proposals, CD/DVD containing all the research proposals and documents to IEC office staff. IEC secretariat will archive one copy in IEC office and other copies will be destroyed after one year.
6. Following documents will be filed and archived with proper label on the top of file for easy identification
    a. Constitution and composition of IEC (Human Studies)-MIMS, Mandya
    b. Curriculum Vitae (CV) of all members of IEC with records of training in Human ethics if any.
    c. Standard Operating Procedures of IEC.
    d. Annual reports
    e. A record of all income and expenses of the EC, including allowances and reimbursements made to the secretariat and EC members;
    f. The published guidelines for submission established by the EC.
    g. Copy of all study protocols with enclosed documents, progress reports, and SAEs.
    h. Agendas and Minutes of all IEC meetings duly signed by the Chairperson / Member secretary.
    i. Copy of all existing relevant national and international guidelines on ethics and laws along with amendments.
    j. Copy of all correspondence with members, Principal Investigators and other regulatory bodies.
    k. Record of all notification issued for premature termination of a study with a summary of the reasons;
    l. Final report of the approved projects, including microfilms, CDs and Video recordings.

XX. Updating members of IEC.

1. All relevant new guidelines should be brought to the attention of the members.
2. The IEC members should be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by

its own members or regular training organized by constituted body/ bodies, so that they become aware of their role and responsibilities. For drug trial review it is preferable to train the IEC members in Good Clinical Practice. Any change in the regulatory requirements should be brought to their attention and they should be aware of local, social and cultural norms, as this is the most important social control mechanism. This is needed for maintaining quality in ethical review

XXI. Terms of reference

Terms of reference will be maintained in the office of IEC. This includes

A. Membership Requirements
B. Terms of Appointment with reference to the duration of the term,
C. The policy for removal, replacement, resignation procedure,
D. Frequency of meetings, and
E. Payment of processing fee to the IEC for review, honorarium/ consultancy to the members/ invited experts / Scientific review members *etc.*

The SOPs will be updated periodically based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage of members could be changed on regular basis. Preferably, IEC would appoint persons trained in bioethics or persons conversant with ethical guidelines and laws of the country. Substitute member may be nominated if meetings have been continuously missed by a member due to illness or other unforeseen circumstances.

XXII. Administration and Management

A full time secretariat and space for keeping records is required for a well-functioning IEC. The members could be given a reasonable compensation for the time spared for reviewing the proposals. There should be provision for allocating reasonable amount of funds for smooth functioning of the IEC.

XXIII. Special Considerations / Protection of Vulnerable Population

While all the above requirements are applicable to biomedical research as a whole irrespective of the specialty of research, there are certain specific concerns pertaining to specialized areas of research which require additional safe guards / protection and specific considerations for the IEC to take note of. Examples of such instances are research involving children, pregnant and lactating women, vulnerable participants and those with diminished autonomy besides issues pertaining to commercialization of research and international collaboration. The observations and suggestions of IEC will be given in writing in unambiguous terms in such instances. ICMR guidelines as applicable will be followed for protection of vulnerable population.

Annexure-1

APPOINTMENT ORDER

Dr/ Mr. / Mrs.:……..…….. Date:……

I am pleased to appoint you as…….of the Institutional Ethics Committee (IEC) (Human Studies) at Mandya Institute of Medical Sciences, Mandya w.e.f ……. for a term of……year / months provided following conditions of appointment are met.

1. You should be willing to publicize your full name, profession &affiliation.
2. You are willing to record all reimbursement for work & expenses, if any, within or related to an EC & make it available to the public upon request.
3. You consent to sign confidentiality agreement between you & the IEC regarding meeting deliberations, applications, information on research participants, & related matters.

The renewal of your appointment will be by consensus & 1 month notice will be necessary prior to resignation of appointment. Terms & Conditions regarding the resignation procedure, disqualification procedures, replacement procedures etc. may be found in the Standard Operating Procedures (SOPs) of IEC,MIMS, Mandya.

You will be paid a sum of Rs 1000/- per sitting as Honorarium for your services rendered & as per the guidelines given in Terms of Reference-IEC, MIMS, Mandya.

We sincerely hope your association with IEC, MIMS, Mandya will be fruitful to the Institute & the Community we serve.

Signature of Appointee

ANNEXURE- 2

MEMBERSHIP CONSENT LETTER

From

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To
The Director,
Mandya Institute of Medical Sciences,
Mandya-571401

Sub: Consent to be a member of Institutional Ethics Committee (Human Studies)-Reg.
Ref: Your Letter No: dated:

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Dear Sir/ Madam,

In response to your letter stated above, I give my consent to become a member of IEC of MIMS, Mandya. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues.

I shall be willing for my name, profession and affiliation to be published.

I shall not keep any literature or study related document with me after the discussion and final review.

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

I here with enclose my CV.

Thanking you,

Yours sincerely,

Signature
Date

Name : ……

Telephone Number……

Email Address……

ANNEXURE-3a

FORMAT FOR SUBMISSION OF PROJECTS INVOLVING RESEARCH IN HUMAN SUBJECTS FOR CLEARANCE BY INSTITUTIONAL ETHICS COMMITTEE OF MIMS, MANDYA

No research project shall be / can be started unless ethics clearance/approval is obtained. Please bear in mind that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor vetted by the Institution Ethics Committee.

All submissions should be made in the prescribed Format to the IEC with signatures of all the investigators.

Forward Eight (8) hard copies and a soft copy(in CD/DVD) of the Research Proposal along with Covering letter, through the Head of the Department with all the required information guided to Chairman IEC to IEC office, MIMS, Mandya.

Project Submission Time: Submissions will be received on all working days. Proposals received till 5th of the month will be processed in the coming Institution Ethics Committee meeting and those received after 5th will be processed in the next Institution Ethics Committee meeting. All meetings of Institution Ethics Committee will be held as far as possible on third or fourth Saturday of January, March, May, July, September, and November. The frequency will change depending upon the number of proposals.

While submitting replies to queries raised by the IEC, the candidates are advised to mention the IEC reference number/s and also attach a copy of the comments of the IEC. Moreover if the approval is required in a particular format, the same may be submitted in a CD/DVD.

Amendment Submission: While submitting amendments in protocols a covering letter should be provided clearly stating the changes and a certificate by the PI that the changes made in the protocol will not hamper the safety of the subject in anyway.

ANNEXURE-3b

Institutional Ethics Committee, MIMS, Mandya

Details need to be Submitted for Initial Review for Research Proposal

1. Covering letter and Forwarding letter from Guide(in case of thesis proposals) through proper channel (Head of the Department)
2. Title of the research proposal
3. Name of the Principal Investigator with qualification and designation
4. Name of the Co-Investigator(s) with qualifications and designation
5. Name of the Institute/ Hospital/ Field area where research will be conducted

} in Separate sheet

6. Protocol of the proposed research: (includes and not limited to) clear research objectives, rationale for undertaking the investigations in human participants in the light of existing knowledge, inclusion and exclusion criteria for entry of participants, precise description of methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded etc.), intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures if any, plan to withdraw or withhold standard therapies in the course of research, plan for statistical analysis of the study, ethical issues in the study and plans to address these issues. **(Separate page with title of the research proposal on top of page)**
7. Proposal should be submitted with relevant enclosures like proforma, case report forms, questionnaires, follow-upcards, participant recruitment procedures and brochures, if any. Informed consent process, including patient information sheet and informed consent form in English and local language(s) are mandatory. Investigator's brochure for trial on drugs/ devices/ vaccines/ herbal remedies and statement of relevant regulatory clearances should be attached. Source of funding and financial requirements for the project has to be detailed.
8. For any drug/ device trial, relevant pre-clinical animal data and clinical trial data from other centers within the country/ other countries, if available.
9. Expected benefits to subjects/volunteers/community. Benefits to other categories if any
10. Explain all anticipated risks (adverse events, injury, discomfort) of the project. Efforts taken to minimize the risks.
11. For trials, proposed compensation and reimbursement of incidental expenses and management of research related and unrelated injury/ illness during and after research period. Description of the arrangements for indemnity, if applicable in study-related injuries and description of the arrangements for insurance coverage for research participants, if applicable.
12. Agreement to report all Serious Adverse Events (SAE)/death to IEC-MIMS, Mandya within the stipulated duration as per Schedule Y.

13. Other financial issues including those related to insurance.
14. An account of storage and maintenance of all data collected during the trial.
15. For international collaborative study details about foreign collaborators and documents for review of Health Ministry's Screening committee(HMSC) or appropriate Committees under other agencies/ authority like Drug Controller General of India(DCGI)
16. For exchange of biological material in international collaborative study a MoU/ Material Transfer Agreement between the collaborating partners.
17. Agreement to comply with the relevant national and applicable international guidelines, Schedule Y guidelines, ICMR guidelines, Good Clinical Practices (GCP) protocols for clinical trials.
18. 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
19. A statement on, probable ethical issues and steps taken to tackle the same like justification for washout of standard drug, or the use of placebo control.
20. Plans for publication of results / positive or negative / while maintaining the privacy and confidentiality of the study participants.
21. Details of Regulatory clearance if required
22. Statement of conflicts of interest, if any
23. Usefulness of the project/trial
24. Agreement to inform the completion of study (within 15 days) and the result summary (within 90 days) to IEC.
25. Curriculum vitae of all the investigators with relevant publications (original research only not review article and case reports) in last five years.
26. Mandatory submission of Certificate of training in ICH-GCP (January 2010 onwards) by PI and Co- investigators in case of Clinical trials or prior participation in Clinical trial as PI or Co-investigator.
27. Mandatory submission of Certificate of training by investigators in Research methodology (January 2010 onwards) / submission of One Published original research article / Acceptance of Original Research article in an Indexed Journal for Non Clinical trial research investigators (January 2010 onwards) .
28. Any other information relevant to the study.
29. Signature of the Principal Investigator with date.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal

ANNEXURE-4

Form to be filled by the Principal Investigator (PI)

(in non-running legible hand writing in blue ball pen only)

for submission to Institutional Ethics Committee (IEC), MIMS, Mandya

(For attachment to each copy of the Research proposal -1 original & 3 photocopies)

Serial No of IEC:

Proposal Title:

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	Name, Designation, Department & Qualifications	**Address Tel &Fax Nos. Email ID**	**No of projects already with Investigator**	**Signature**
PI				
Co-PI				
Co-PI				
Co-PI				

Please attach detailed Curriculum Vitae of all Investigators
(with subject specific publications limited to previous 5 years)

Tick appropriately

Sponsor Information				
1. Indian	a)Government ☐ b) Private ☐	Central ☐	State ☐	Institutional☐
2. International	Government ☐	Private ☐	UN agencies☐	
3. Industry	National ☐		Multinationa☐	
Contact Address of Sponsor:				
Total Budget :				
Who will bear the cost of investigation / implants drugs / contrasts?	1. Patient 2. Project 3. Exempted ***4.*** Other Agencies			

1.Status of Review: New ☐ Revised☐		
2.Type of Study : Cross sectiona☐ case contro☐ cohort Clinica.☐ Trial Review☐ Participating Centre: Single cente☐ Multi-centric☐ Others (Specify)……..		
3. Clinical Trials: **Drug /Vaccines/Device/Herbal Remedies :** i. Does the study involve use of: Drug☐ Device☐ Vaccines☐ Indian Systems of Medicine/ Alternate System of Medicine☐ Any other☐		
ii. 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? **If yes**, whether DCGIs /Any other Regulatory authority's Permission is obtained? **If yes,** Date of permission :	*Yes* *Yes*	*No* *No*
iv. Is it an Investigational New Drug? **If yes,** IND No	*Yes*	*No*
a). Investigators 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? **If Yes**, attach details	*Yes*	*No*

5. **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):		
6. **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☐		
vi.Vulnerable subjects Yes☐ No☐ (Tick the appropriate boxes)		

Pregnant women	children	elderly
fetus	illiterate	handicapped
Terminally ill	Seriously ill	Mentally ill

vii.Special group subjects Yes ☐ No ☐
(Tick the appropriate boxes)

captives	institutionalized	employees
students	nurses/dependent	armed
Any other	staff	forces

6. Privacy and confidentiality

i. Study involves –

Direct Identifiers☐ Indirect Identifiers/coded☐ Completely anonymised☐

ii. Confidential handling of data by staff Yes☐ No☐

7.Use of biological/hazardous materials	Yes	No
i. Use of fetal tissue or abortus	Yes	No
ii. Use of organs or body fluids	Yes	No
iii.Use of recombinant/gene therapy	Yes	No
If yes, has Department of Biotechnology(DBT) approval for r DNA products been obtained?	Yes	No
iv.Use of pre-existing/stored/left over samples	Yes	No
v. Collection for banking/future research	Yes	No

vi. Use of ionizing radiation/radioisotopes	Yes	No
If yes, has Bhaba Atomic Research Centre (BARC) approval For Radioactive Isotopes been obtained?	Yes	No
vii. Use of Infectious/bio hazardous specimens	Yes	No
viii. Proper disposal of material	Yes	No
ix. Will any sample collected from the patients be sent abroad?	Yes	No
If Yes, justify with details of collaborators		
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):		
Facility not available in India		
Facility in India inaccessible		
Facility available but not being accessed.		
If so, reasons		

8.Consent : *Written☐ Oral ☐ Audio-visual☐

i. Consent form : (tick the included elements)

Understandable language	Alternatives to participation
Statement that study involves research	Confidentiality
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☐ Research staff☐

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? ii. Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk More than minimum risk High risk Iii .Is there a benefit a) to the subject ? Direct ☐ Indirect ☐ b)Benefit to society	Yes Yes	No No
11. DataMonitoring i. Is there a data & safety monitoring committee/Board (DSMB)? ii. Is there a plan for reporting of adverse events? **If Yes,** reporting is done to :Sponsor, Ethics Committee ,DSMB iii. Is there a plan for interim analysis of data? vi. Are there plans for storage and maintenance of all trial database? **If Yes,** for how long?	Yes Yes Yes Yes	No No No 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 Sponsc☐ by Investigato☐ by insuranc☐ by any other company	Yes	No
14. Do you have conflict of interest? (financial / nonfinancial) **If Yes, specify :**	Yes	No
15. Conflict of interest for any other investigator(s) (if yes, please explain in brief)	Yes	No
16**.** Participant Information Sheet attached	Yes	No
17**.** Participant Informed Consent Form attached	Yes	No
18**.** Whether any work on this project has started or not?	Yes	No

Checklist for attached documents

Covering letter, through proper channel	
Project proposal 08 Copies	
Curriculum Vitae of Investigators	
Brief description of proposal	
Patient information sheet	
Informed Consent form	
Investigator s brochure	
Copy of advertisements/Information brochures	
Copy of clinical trial protocol and/or questionnaire	
HMSC/DCGI/DBT/BARC clearance if required	
Undertaking that the study shall be done in accordance with ICMR and GCP guidelines	
In case of multi-centric study, IEC clearance of other centres must be provided	
Definite undertaking as to who will bear the expenditure of injury related to the project	
If an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines)	
Permission to use copyrighted Questionnaire/ proforma	
Investigator should provide undertaking what they will do with the left over sample tissue	
Statement of conflict of Interest	
ICH-GCP training Certificate	
Certificate of Training in Research Methodology / Publication in Indexed Journal (research Article only)	
NOC/ Permission /Approval certificate by Medical Superintendent-MIMS if needed	
Others	

ANNEXURE-5

Ongoing Approved Research Review Submission Form

1. Reference number
2. Month/Year of approval
3. Number of ongoing review
4. Title of the research proposal
5. Name of the Principal Investigator (PI) with qualification and designation
6. Name of the Co-investigator (s)(Co-PI)with qualification and designation
7. Duration of the Project
8. Source of funding & financial allocation for the project/trial
9. Has subject recruitment begun?
10. If subject recruitment has not begin, give reasons and proceed toNo:20
11. How many subjects have been screened?
12. How many subjects have been recruited?
13. How many more to be recruited
14. Is subject recruitment continuing?
15. Are there any dropouts?
16. Are subjects still receiving active intervention?
17. Have there been any adverse events? If yes, give details
18. Have there been any Serious Adverse Events adverse events? If yes, give details.
19. Have there been any unanticipated study-related problems?
20. Is there anyone risk or benefit information? If yes, give details.
21. Are there any interim changes to the protocol or consent form? If yes, give details including submission of revised protocol land consent form for approval
22. Does the scientific literature indicate changes in knowledge relevant to the conduct of the study?
23. List of attachments for review, if any
24. Remarks, if any
25. Signature of the Principal Investigator with date.

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal.

ANNEXURE-6

Format for ***submission of revised / additional documents, protocols and information Regarding already approved projects***

to be submitted by the Principal Investigator (PI)

(Two copies of this form along with the revised documents to be submitted)

1. **IEC Reference No:**
2. **Approval Date and Number:**
3. **Title:**
4. **Principal Investigator:**
5. **Purpose of this submission:**
6. **New documents being submitted:** Please list the documents being submitted along with the differences from the previously approved documents in a tabular form as below:

S.No	List of Documents being submitted	List the modifications/revisions made from previously approved proposal, wherever applicable

Place: Signature of PI/Collaborator

Date: Name:

ANNEXURE-7

Six monthly progress Project

IEC Reference No:.....

Study title:

.....
.....
.....

Name of the Principal Investigator; .....

Designation / Department: .....

Duration of Study: .....

Date of Starting of the Study: .....

Period of Six monthly progress report: from……to……

Progress:

Side Effect if any:

Amendments if any:

Discontinuation reasons:

Progress:

Signature of Principal Investigator

Date:

ANNEXURE-8

PARTICIPANT INFORMATION SHEET (PIS)

(FOR COMPLETE DETAILS SEE ICMR's ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH ON HUMAN PARTICIPANTS-2006)

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 Kannada, in a simple layman's language which can be understood by them, in a narrative form, directed to the participant / LAR, covering all the points** :

1. Study Title
2. Aims and methods of the research study
3. Expected duration of participation
4. The benefits to be expected from the research to the participant or to others
5. Any risk or discomfort to the participant associated with the study
6. Maintenance of confidentiality of records
7. Provision of free treatment for research related injury
8. Compensation of subjects for disability or death resulting from such injury
9. Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would be entitled otherwise
10. Amount of blood sample (quantity in tea spoon full) to be taken
11. Costs and source of investigations, disposables, implants and drugs/ contrast media
12. Telephone number/ contact number of Principle investigator and Co-Investigator at the top of each page
13. In case of a drug trial:
    a. The chemical name of the drug, date of its manufacturing and batch number must be mentioned
    b. Initial bioequivalence study of the drug/ references should be provided 14.Self-certification should be given that the translation to vernacular language is correct
14. Self-certification should be given that the translation to vernacular language is correct.

ANNEXURE-9

PARTICPANT INFORMED CONSENT FORM (P-ICF)

(FOR COMPLETE DETAILS SEE ICMR's ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH IN HUMAN PARTICIPANTS-2006)

Protocol Study number:_____

Patient identification number for this study: _____

Title of the project: _____

_____

Name of Principal investigator: _____Tel. No(s)._____

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 from the study 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 MIMS, Mandya. I give permission for these individuals to have access to my records.

I agree to take part in the above study ---------- Signatures / Left Thumb Impression)	Date: Place:

Name of 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

Witness- 1	Witness -2
Signature	Signature
Name:	Name:
Address:	Address:

NB:Three copies should be made, one each for (1) Patient (2) Researcher (3) Institution
(Investigators are advised to prepare the Kannada translation in simple understandable sentences)

ANNEXURE-10

Data Elements for reporting serious adverse events occurring in a clinical trial

1.Patient Details

Initials & other relevant identifier (hospital/OPD record number etc.)* Gender
Age and/or date of birth
Weight
Height

2.Suspected Drug(s)

Generic name of the drug*
Indication(s) for which suspect drug was prescribed or tested
Dosage form and strength
Daily dose and regimen (specify units-e.g., mg, ml, mg/kg)
Route of administration
Starting date and time of day
Stopping date and time, or duration of treatment

3.Other Treatment(s)

Provide the same information for concomitant drugs (including nonprescription/OTC drugs)and non-drug therapies ,as for the suspected drug(s).

4.Details of Suspected Adverse Drug Reaction(s)

Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.*
Start date (and time) of onset of reaction
Stop date (and time)or duration of reaction
Dechallenge and rechallenge information
Setting(e.g., hospital, out-patient clinic, home, nursing home)

5.Outcome

Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted
For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; Any post-mortem findings.
Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.

*6.Details about the Investigator**

Name
Address
Telephone number
Profession (specialty)

Date of reporting the event to Licensing Authority:
Date of reporting the event to Ethics Committee over-seeing the site:

Signature of the Investigator

Note :Information marked* must be provided.

Format for review from the Scientific Review Board / ISC

(filled by legible Hand writing only, to be attached by all the reviewers)

Review of scientific design of the research Proposals by three reviewers or by the committee

Technical appropriate of the proposed study (comments on the Title, Objectives, methodology adopted ,scientific design validity, adequate to answer the questions posed.etc)

IEC Reference No:
Title of the protocol:
Comments
Final Comments: Approved / Approved with corrections / Rejected
Reviewed by Name: …… Signature Designation and Department Date …… ……

IEC reference No:.....	Date of Submission:.....

Date: .....

From
(Name of Principal Investigator)
.....
.....
.....
.....

To:
The Chairman.
Institutional Ethics Committee
MIMS,Mandya.

THROUGH PROPER CHANNEL

Respected Sir,

Sub: submission of research proposal for Ethical Clearence-regarding

*****

With respect to the above subject, I am herewith submitting research proposal titled "..... ....." to you for review and ethical clearance. Kindly review and do the needful.

I am herewith enclosing Demand Draft payable at Mandya an amount Rs……dated…….from ……...Bank.

Thanking you,

Yours truly,

Signature of PI
(Name of PI)

Title of the study

“.....
.....”

Details of all the researchers

Name of Researcher 1	
Designation	
Department	
Phone No	
Signature	
Name of Researcher 2	
Designation	
Department	
Phone No	
Signature	
Name of Researcher 3	
Designation	
Department	
Phone No	
Signature	
Name of Researcher 4	
Designation	
Department	
Phone No	
Signature	
Address where the study is done	

IEC reference No:.....

Title of the study

“.....

.....”

Introduction and need for the study

Literature review

Aims, Objectives

Materials and Methodology

Plan of Statistical Analysis

References

ANNEXURE-4

Form to be filled by the Principal Investigator (PI)

(in non-running legible hand writing in blue ball pen only)

for submission to Institutional Ethics Committee (IEC), MIMS, Mandya

(For attachment to each copy of the Research proposal)

Serial No of IEC:

Proposal Title:

.....
.....
.....
.....
.....

	Name, Designation, Department & Qualifications	**Address Tel &Fax Nos. Email ID**	**No of projects already with Investigator**	**Signature**
PI				
Co-PI				
Co-PI				
Co-PI				

Please attach detailed Curriculum Vitae of all Investigators (with subject specific publications limited to previous 5 years)

Tick appropriately

Sponsor Information				
1. Indian	a)Government ☐ b) Private ☐	Central ☐	State ☐	Institutional☐
2. International	Government ☐	Private ☐	UN agencies☐	
3. Industry	National ☐		Multinational☐	
Contact Address of Sponsor:				
Total Budget :				
Who will bear the cost of investigation / implants drugs / contrasts?	1. Patient 2. Project 3. Exempted ***1.*** Other Agencies			

1.Status of Review: New ☐ Revised☐		
2.Type of Study : Cross sectional☐ case control☐ cohort Clinical☐ Trial Review☐ Participating Centre: Single center☐ Multi-centric☐ Others (Specify)……..		
3. Clinical Trials: **Drug /Vaccines/Device/Herbal Remedies :** i. Does the study involve use of: Drug☐ Device☐ Vaccines☐ Indian Systems of Medicine/ Alternate System of Medicine☐ Any other☐		
ii. 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? **If yes**, whether DCGIs /Any other Regulatory authority's Permission is obtained? **If yes,** Date of permission :	*Yes* *Yes*	*No* *No*
iv. Is it an Investigational New Drug? **If yes,** IND No	*Yes*	*No*
a). Investigators 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? **If Yes**, attach details	*Yes*	*No*
2. **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):

3. **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☐

vi. Vulnerable subjects Yes☐ No☐
(Tick the appropriate boxes)

Pregnant women	children	elderly
fetus	illiterate	handicapped
Terminally ill	Seriously ill	Mentally ill

vii. Special group subjects Yes ☐ No ☐
(Tick the appropriate boxes)

captives	institutionalized	employees
students	nurses/dependent	armed
Any other	staff	forces

6. Privacy and confidentiality

i. Study involves –
Direct Identifiers☐ Indirect Identifiers/coded☐ Completely anonymised☐

ii. Confidential handling of data by staff Yes☐ No☐

7.Use of biological/hazardous materials	Yes	No
i. Use of fetal tissue or abortus	Yes	No
ii. Use of organs or body fluids	Yes	No
iii. Use of recombinant/gene therapy	Yes	No
If yes, has Department of Biotechnology(DBT) approval for r DNA products been obtained?	Yes	No
iv. Use of pre-existing/stored/left over samples	Yes	No
v. Collection for banking/future research	Yes	No
vi. Use of ionizing radiation/radioisotopes	Yes	No
If yes, has Bhaba Atomic Research Centre (BARC) approval		

For Radioactive Isotopes been obtained?	Yes	No
vii. Use of Infectious/bio hazardous 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** a. Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration? b. Sample will be sent abroad because (Tick appropriate box): Facility not available in India Facility in India inaccessible Facility available but not being accessed. If so, reasons	Yes Yes	No No

8.Consent : *Written☐ Oral ☐ Audio-visual☐

i. Consent form : (tick the included elements)

Understandable language	Alternatives to participation
Statement that study involves research	Confidentiality
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☐ Research staff☐

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,** Minimal or no risk More than minimum risk High risk Iii .Is there a benefit a) to the subject ? Direct ☐ Indirect ☐ b)Benefit to society	Yes	No
11. DataMonitoring i. Is there a data & safety monitoring committee/Board (DSMB)? ii. Is there a plan for reporting of adverse events? **If Yes,** reporting is done to :Sponsor, Ethics Committee ,DSMB iii. Is there a plan for interim analysis of data? vi. Are there plans for storage and maintenance of all trial database? **If Yes,** for how long?	Yes Yes Yes Yes	No No No 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 Sponsc☐ by Investigato☐ by insuranc☐ by any other company	Yes	No
14. Do you have conflict of interest? (financial / nonfinancial) **If Yes, specify :**	Yes	No
15. Conflict of interest for any other investigator(s) (if yes, please explain in brief)	Yes	No
16**.** Participant Information Sheet attached	Yes	No
17**.** Participant Informed Consent Form attached	Yes	No
18**.** Whether any work on this project has started or not?	Yes	No

Checklist for attached documents

Covering letter, through proper channel	
Project proposal 08 Copies	
Curriculum Vitae of Investigators	
Brief description of proposal	
Patient information sheet	
Informed Consent form	
Investigator s brochure	
Copy of advertisements/Information brochures	
Copy of clinical trial protocol and/or questionnaire	
HMSC/DCGI/DBT/BARC clearance if required	
Undertaking that the study shall be done in accordance with ICMR and GCP guidelines	
In case of multi-centric study, IEC clearance of other centres must be provided	
Definite undertaking as to who will bear the expenditure of injury related to the project	
If an insurance cover is intended, Insurance certificate must be provided (as per ICMR guidelines)	
Permission to use copyrighted Questionnaire/ proforma	
Investigator should provide undertaking what they will do with the left over sample tissue	
Statement of conflict of Interest	
ICH-GCP training Certificate	
Certificate of Training in Research Methodology / Publication in Indexed Journal (research Article only)	
NOC/ Permission /Approval certificate by Medical Superintendent-MIMS if needed	
Others	

CV of all researchers

Check list with enclosures