# Standard Operating Procedures (SOP)

# For

# Institute Ethics Committee,

# Sri Aurobindo Institute of Medical Sciences,

# Indore

# Standard Operative Procedure

## VERSION HISTORY

| Version No. | Date | Change made by after approval of | Change made |
|---|---|---|---|
| 0.1 | March 2008 | IEC members meeting 26th March 2008 | First of SOP |
| 1.0 | March 2009 | IEC members | Point number 13 on scope of review expanded. |
| 2.0 | May 2010 | IEC members | 1. Name changed to Institute Ethics Committee, SAIMS<br>2. Point number 11 modified-more frequent meeting if number of proposals demand.<br>3. Secrecy undertaking, CV form modified<br>4. Guidelines amended<br>5. Constitution added |
| 3. | August 2013 | IEC members meeting held 22 aug 2013 | 1. Day and time of meeting for review amended to ~~Thursday~~ Saturday 3.30 pm<br>2. Under point 19 para 3 is added<br>3. Point 21 deleted-?<br>4. Point 23 to 25 added |

# Standard Operating Procedure (SOP) for Institute Ethics Committee, Sri Aurobindo Institute of Medical Sciences, Indore

## 1. Objective

The objective of Standard Operating Procedure (SOP) is to ensure quality and consistency in review of clinical research proposals and to follow the ICMR and national ethical guidelines for biomedical research on human subjects.

## 2. Functions of Institutional Ethics Committee (IEC)

IEC should provide independent, competent and timely review of the ethics of proposed studies before the commencement of a study and regularly monitor the ongoing studies. IEC will review and approve all research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of research participants irrespective of the source of funding. The goals of research, however important, should never be permitted to override the health and well being of the research subjects. The IEC will ensure 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 a proposed study. It will look into the aspects of informed consent process, risk benefit ratio, distribution of burden/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 periodic reports, final report and site visits etc. The committee will also ensure compliance with all regulatory requirements, applicable guidelines and laws.

## 3. Composition of IEC

IECs shall be multidisciplinary and multi-sectorial in composition. The number of members in the committee shall be kept small (7-11 members) as a large committee makes it difficult in reaching consensus and in having the presence of all the members. The external members shall be in majority to ensure the independence of the committee. The Chairperson of the committee shall be from outside the Institution and not Head/former Head of SAIMS. The Member Secretary, drawn from SAIMS itself, shall conduct the business of the Committee. Other members will be a mix of medical and nonmedical scientific and non-scientific persons including general public to reflect the differed viewpoints.

The composition may be as follows:-

1. Chairperson
2. Basic medical scientists
3. Clinicians
4. Legal expert
5. Social scientist/representative of non-governmental voluntary agency
6. Educated person from the community
7. Member-Secretary

IEC shall have majority of its members from other institutions. They could be drawn from any public or private institute from anywhere in the country. There shall be adequate representation of age, gender, community etc. in the Committee to safeguard the interests and welfare of all sections of the society. The Committee cannot consist entirely of men or entirely of women.

**4. Constitution of IEC**

The Chairman of the Institute shall constitute the IEC, in consultation with the Academic Head (Dean) in the following pattern:

1. Chairperson- from outside the Institute
2. Member Secretary from the Institute
3. 5-7 members from different specialties as specified above, some of them should be from the Faculty of the Institute.

The committee will be normally reconstituted every 3 years

**5. Membership Duration and Responsibilities**

There will be no bar on the members serving for more than one term but it is desirable to have around one third fresh members.

1. The duration of the membership will be 3 years
2. There will be no bar on the members serving for more than one term but it is desirable to have around one third fresh members.
3. A member can be replaced in the event of long-term non-availability (three consecutive meetings). Authority to replace the member shall be with the Chairman.
4. Members should maintain confidentiality of all discussions during the meeting and sign a confidentiality form at the start of their term. Each member of the committee will submit a declaration to maintain the confidentiality of the documents submitted to them during their membership period.
5. Conflict of interest, if any, shall be declared by members of the IEC at the beginning of every meeting.

**6. Quorum Requirements**

A minimum of 5 members including at least three outside members is required for quorum. All decisions should be taken in meetings and not by circulation of project proposals.

**7. Offices/Conduct of the Meeting**

The Chairperson will conduct all meetings of the IEC. If for reasons beyond control, the Chairperson is not available, an alternate Chair person will be elected b the member present from among themselves. The Member Secretary will be responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get them approved by the Chairperson before communicating to the PI.

**8. Independent Consultants-**

IEC may call upon subject expert consultants for review of selected research protocols. 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 not take part in the decision making process.

**9. Application Procedure**

1. The research proposals shall first, be peer-reviewed by presenting it in a research committee meeting as constituted by the Head of Academics/Dean
2. All proposals should be submitted in the *prescribed application form*, copies of which will be available with the Member Secretary. They will also be put on website.
3. All relevant documents should be enclosed with application.
4. The required number of copies of the proposal along with the application and documents in prescribed format duty signed by the PI and co- investigators / Collaborators should be forwarded by the Head of the Department.
5. The Member_Secretary will acknowledge the receipt and indicate any lacunae. Missing information should be supplied within two weeks.
6. The date of meeting will be intimated to the PI who should be available to offer clarifications if necessary.
7. The decision of IEC 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.

**10. Documentation**

All research proposals should be submitted with the following documents:

1. Title of the project
2. Names of the PI and Co-investigators with designation.
3. Name of any other Institute/Hospital/Field area where research will be conducted.
4. Approval of the Head of the Department.
5. Protocol of the proposed research.
6. Ethical issues in the study and plans to address these issues.
7. Proposal should be submitted with all relevant annexure like proforma, case report forms, questionnaires, follow—up cards, etc. to be used in the study.
8. Patient information sheet and informed consent form in English/Hindi and local language(s) should be enclosed. The patient information sheet should provide adequate and complete information in understandable language. It should also assure that any new information that becomes relevant during the trial and is related to their participation will be given to them. The consent form should be as per schedule Y published in Gazette of India (2005).
9. For any drug/device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country/other countries, if available.

10. Any regulatory clearances required, copy of clearances be obtained. This is necessary for new drug/device not approved for marketing in India, justification for sending of biological samples outside India and use of radioactive pharmaceuticals in clinical studies.
11. Source of funding and Budget along with the supporting documents.
12. Indemnity issues including insurance for the compensation to the participants etc.
13. An undertaking to immediately report Serious Adverse Events (SAE) to IEC.
14. Statement of conflicts of interest, if any
15. Plans for publication of results-positive or negative-while maintaining the privacy and confidentiality of the study participants.
16. Any other information relevant to the study.
17. Agreement to submit annual/interim progress report and final report at the end of study.
18. The PI should provide the details of other ongoing research projects (Title of the project, Date of starting and duration, source and amount of funding).

## 11. Review Procedure

1. Meetings of IEC shall be held on scheduled intervals as prescribed (once in 3 months, on Thursday at 2.30 PM (vide decision IEC meeting Aug. 2013) for which the dates will be decided at the end of previous meeting). Additional meetings will be held as and when necessary. IEC Member agreed to meet more frequently (even monthly) if there are sufficient number of proposals (vide decision IEC meeting March 2009.
2. The proposals will be sent to members at least 2 weeks in advance.
3. Decisions will be taken by consensus after discussions, and voting will be done if necessary.
4. PI should be available during the meeting and may be invited to offer clarifications.
5. Independent consultants/Experts may be invited to offer their opinion on specific research proposals. They will not participate in voting, however.
6. The decisions of the meeting shall be recorded in the minute's book and shall be confirmed during the next meeting with signature of Chairperson at each page. The minutes of meeting will be circulated to all members, Chairman and Vice-chairman of SAIMS and to Dean, SA1MS after approval from Chairperson

12. Element of Review

1. Scientific design and conduct of the study.
2. Approval of scientific review committee and regulatory agencies.
3. Assessment of predictable risks/harms and potential benefits.
4. Procedure for selection of subjects including inclusion/exclusion, withdrawal criteria and other issues like sample size and advertisement details.
5. Management of research related injuries, adverse events and compensation provisions.
6. Justification for placebo in control arm, if any.
7. Availability of products to the trial subjects after the study, if applicable.
8. Patient information sheet and informed consent form in English/Hindi and local language.
9. Protection of privacy and confidentiality of subjects.
10. Involvement of the community, wherever necessary.
11. Protocol and proforma of the study including the consent form.
12. Plans for data analysis and reporting.
13. Adherence to all regulatory requirements and applicable guidelines.
14. Competence of investigators, research and supporting staff.
15. Facilities and infrastructure including budget.

13.

**A. Exemption from review**

Proposals which present less than minimal risk fall under this category as may be seen in following situations:

i. Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exceptions:

i. When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.

ii. When interviews involve direct approach or access to private papers.

**B. Expedited Review**

The Proposals that (1) present no more than minimal risk to human subjects, and (2) Involve only procedures listed in one or more of the categories of ICMR Guidelines 2006. The Member- Secretary and the Chairperson of the IEC or designated member of the Committee or Subcommittee of the IEC may do expedited review only if the protocols involve -

1. Minor deviations from originally approved research during the period of approval (usually of one year duration).
2. Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
3. Research activities that involve only procedures listed in one or more of the following categories:

a. Clinical studies of drugs and medical devices only when -

i. Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or

ii. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.

4. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.
5. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and **the same participants should not be** included in the clinical trial that may be initiated later based on the findings of the pilot study.

a. Research on interventions in emergency situation:

When proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (LND) / devices/ vaccine to provide emergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients —

i. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative/ legal guardian when available later;
ii. When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCGI;
iii. Only if the local TEC reviews the protocol since institutional responsibility is of paramount importance in such instances.
iv. if Data Safety Monitoring Board4DSMB) is constituted to review the data;

**b. Research on disaster management** -

A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or state(s). It may be periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

i.) Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible vplication in future disaster situations.
ii.) Disaster-affected community participation before and during the research is essential and its representative or advocate must be identified.
iii.) Extra care must be taken to protect the privacy and confidentiality of participants and communities.
iv.) Protection must be ensured so that only minimal additional risk is imposed.
v.) The research undertaken should provide direct or indirect benefits to the participants, the disaster-affected community or future disaster- affected population and *a priori* agreement should be reached on this, whenever possible, between the community and the researcher.
vi.) All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.
vii.) Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

C. Full Review

All research presenting with more than minimal risk, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable population and special groups shall be subjected to full review by all the members.

While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

a. Collection of blood samples by finger prick, heel prick, ear prick, or veni-puncture:

i. from healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8 week period and frequency of collection is not more than 2 times per week;

ii. from other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg, whichever is lesser is drawn in an 8 week period and not more than 2 times per week;

iii. From neonates depending on the haemodynamics, body weight of the baby and other purposes not more than 10% of b1oo4 is drawn within 48 —72 hours. If more than this amount is to be drawn it becomes a risky condition requiring infusion/blood transfusion;

iv. Prospective collection of biological specimens for research purposes by noninvasive means. For instance:

1. skin appendages like hair and nail clippings in a non-disfiguring manner;
2. dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth;
3. excreta and external secretions (including sweat);
4. uncannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue;
5. placenta removed at delivery;
6. amniotic fluid obtained at the tirr.11)f rupture of the membrane prior to or during labor;
7. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
8. Sputum collected after saline mist nebulization and bronchial lavages.

b. Collection of data through noninvasive procedures routinely employed in clinical practice. Where medical devices are employed, they must be cleared/ approved for marketing, for instance –

i. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy;

ii. weighing or testing sensory acuity;

iii. magnetic resonance imaging;

iv. electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow,

v. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

c. Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.

d. Collection of data from voice, video, digital, or image recordings made for research purposes.

e. Research on individual or group characteristics or behavior not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Proposals which are recommended for, minor revisions will be reviewed by a sub committee appointed by the IEC for clearance and approved by the Chairperson. The approvals will be reported in the next IEC meeting by Member Secretary. The revised form of proposals requiring major changes will be reviewed at the next ethics committee meeting. Rejected proposals may be reconsidered only if a very strong background is there.

14. Decisions Making

1. A member shall withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises. This shall be indicated to the chairperson prior to the review of the application and recorded in the minutes.
2. Only members will make the decision. The decisions shall be taken in the absence of investigators, representatives of sponsors, consultants.
3. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
4. Revised proposals may be subjected to an expedited review.
5. All approved proposals will be subject to the following standard conditions. Additional conditions may be added by the IEC.

   i. PI should submit annual report of the ongoing project on format prescribed by the Institute, to the IEC.

   ii. The final report of the completed study should be submitted by PI.

   iii. The PI should highlight the changes in the protocols/brochures/informed consent form etc, being amended from the previous documents while submitting amended documents to IEC.

**15. Communicating the Decision**

1. Decision will be communicated to PI by the Member Secretary in writing within 2 weeks of meeting.
2. Suggestions for modifications and reasons for rejection shall be communicated to the PI.

**16. Memorandum of Understanding and Indemnity Agreement for Sponsored Drug/Device/Collaborative Trials**

After the approval from IEC, the sponsor/CRO will submit the clinical trial agreement/Memorandum of Understanding and Indemnity Agreement document on Rs. 100 stamp paper separately (two copies) to the Institute which will be signed by sponsor and the Chairman, SAIMS with the counter signature of PI. As per existing policy of the Institute, there will be 25% overhead charges to the total cost of the trial/per patient cost. The drug trial shall be started by the PI after the agreement is signed by both the parties as well as DCGI and required regulatory approvals are available for the concerned trial.

## 17. Follow up Procedures

1. Annual report should be submitted by the PI on prescribed format along with comments.
2. Final report should be submitted at the end of study on prescribed format including a copy of the report which has been ,i-lit to sponsoring agency.
3. All SAEs and the interventions undertaken should be intimated immediately to IEC. The PI should submit the SAEs reported by other centers from time to time to the Member Secretary for information to IEC along with comments if any action is required in the current study.
4. Protocol deviation, if any, should be informed with adequate justifications.
5. Any amendment to the protocol should be submitted for approval.
6. Any new information related to the study should be communicated to IEC.
7. Premature termination of study should be notified with reasons along with summary of the data obtained so far.
8. Change of investigators should be done with the approval of IEC.

## 18. Record Keeping and Archiving

1. Curriculum Vitae (CV) of all members of IEC.
2. Minutes of all meetings duly signed by the Chairperson. Copy of all correspondence with members, researchers and other regulatory bodies would be archived.
3. Copy of existing relevant national and international guidelines on research ethics and laws along with amendments.
4. All study related documents (study protocols with enclosed documents, progress reports, and SAEs.) Should be archived for minimum of ten years after the completion of study. A copy of filled CRF shall remain with the PI for minimum of fifteen years.
5. Final report of the approved projects.

19. Updating IEC Members and policy regarding training for new and existing committee members.

1. All relevant information on ethics will be brought to the attention of the members of IEC by the Member Secretary. Members are required to keep the office of IEC with their most recent contact number and email address. Any change should be brought to the notice of member secretary at the earliest.

2. Institute Members will be encouraged to attend national and international training programs/conferences/seminars in the field of research ethics to help in improving the quality of research protocols/ethics committee submissions and review. The EC members are encouraged to keep abreast of all national and international developments in ethics through orientation course on related topic.

3. For drug trial review IEC members will be given training in Good Clinical Practice. Any change in the regulatory requirements will be brought to their attention and they will be made aware of local, Social and cultural norms, as these are the most important social control mechanism.

**20. Recognized Prior Review**

Consistent with the spirit underlying Mutual Acceptance, IEC SAIMS will offer recognitions of prior review and approval by selection of other research sites/Institutes across India.

21. Fees: Will be fixed as per decision by the Institute.

22. Audit: Annual Audit will be done by the Auditor of the Institute

**23. Compensation for participation**

Participants will be paid for the inconvenience and time spent, and should be reimbursed for expenses incurred, in connection with their participation in research but would be reasonable so that it should not be included as benefit. They will also receive free medical services. During the period of research if the participant requires treatment for complaints other than the one being studied necessary free ancillary care or appropriate referrals will be provided. However, payments will not be so large or the medical services so extensive as to make prospective participants consent readily to enroll in research against their better judgment, to label it as undue inducement. All payments, reimbursement and medical service, that is to be provided to research participants, will be approved by the IEC.

## 24. CONFLICT OF INTEREST:-

Research in alliance with industries/ commercial companies require a strong review to probe possible conflicts of interest between scientific responsibilities of researcher and business interest (ownership or part-ownership of a company developing a new product). In cases where the review board/committee determines that a conflict of interest may damage the scientific integrity of a project or cause harm to research participants, the board/ committee will advise accordingly. Significant financial interest means anything of monetary value that would reasonably appear to be a significant consequence of such research including salary or other payments for services like consulting fees or honorarium per participant; equity interests in stocks, stock options or other ownership interests and intellectual property rights from patents, copyrights and royalties from such rights. The investigators should declare such conflicts of interest in the application submitted to IEC for review. Institutions and IECs need self-regulatory processes to monitor, prevent and resolve such conflicts of interest. The IEC can determine the conditions for management of such conflicts in its SOP manual. Prospective participants in research should also be informed of the sponsorship of research, so that they can be aware of the potential T6i- conflicts of interest and commercial aspects of the research. Those who have also to be informed of the secondary interest in financial terms should include the institution, IEC, audience when presenting papers and should be mentioned when publishing in popular media or scientific journals.

Undue inducement through compensation for individual participants, families and populations should be prohibited. This prohibition however, doe § not include agreements with individuals, families groups, communities or populations- that foresee technology transfer, local training, joint ventures, provision of health care reimbursement, costs of travel and loss of wages and the possible use of a percentage of any royalties for humanitarian purposes. Undue compensation would include assistance to related person(s) for transport of body for cremation or burial, provision for insurance for unrelated conditions, free transportation to and fro for examination not included in the routine, free trip to town if the participants are from rural areas, free hot meals, freedom for prisoners, free medication which is generally not available, academic credits and disproportionate compensation to researcher / team/ institution. However, in remote and inaccessible areas some of the features mentioned above may be a necessity and culture specific. Therefore, the IEC should examine this on a case-by-case basis, as some of these elements may be justifiable for collecting vital data for national use or necessary to find if some interventions may significantly have direct impact on health policies.

## 25. Standard operating procedures to be followed by the committee for vulnerable population.

The vulnerable population not only includes Pregnant Women, Children, Elderly, Fetus, neonates but also illiterate, Handicapped, Terminally ill, Seriously ill, Mentally challenged, Economically & socially backward, Captives, Institutionalized persons, Students, Nurses/Dependent Staff , Armed Forces and population facing natural or manmade disaster.

While all the requirements laid down in SOP version 1 dated Aug, 2013 are applicable to biomedical research as a whole irrespective of the specialty of research, there are certain specific concerns pertaining to specialised areas of research which require additional safe guards / protection and specific considerations. While obtaining data/samples from vulnerable subgroups with reduced autonomy, Ethics Committee will ensure that informed consent be obtained from legally authorized representatives in the presence of impartial witness. Ethics committee will take note of following special situation and expect various principal investigators to address these situations adequately before granting approval for various research projects. Provision for identification of vulnerable groups has been made in Proforma for submission of clinical research protocols to Institutional ethics committee.

## SPECIAL GROUPS AS RESEARCH PARTICIPANTS

1. Pregnant or nursing women:- Pregnant or nursing women should in no circumstances be the participant of any research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about the foetus, pregnancy and lactation. As a general rule, pregnant or nursing women should not be participants of any clinical trial except such trials as are designed to protect or advance the health of pregnant or nursing women or foetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable participants.
   a. The justification of participation of these women in clinical trials would be that they should not be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits. Example of such trials are, to test the efficacy and safety of a drug for reducing perinatal transmission of HIV infection from mother to child, trials for detecting foetal abnormalities and for conditions associated with or aggravated by pregnancy etc. Women should not be encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breast-feeding to the nursing child should be properly assessed except in those studies where breast feeding is harmful to the infant. Compensation in terms of supplying supplementary food such as milk formula should be considered in such instances.
   b. Research related to termination of pregnancy: Pregnant women who/desire to undergo Medical Termination of Pregnancy (MTP) could be made participants for such research as per The Medical Termination of Pregnancy Act, GOI, 1971.
   c. Research related to pre-natal diagnostic techniques : In pregnant women such research should be limited to detect the foetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOT, 1994 and not for sex determination of the foetus.

2. *Children* : Before undertaking trial in children the investigator must ensurethat -

   a. Children will not be involved in research that could be carried out equally well with adults;

b. The purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug the study in children should always be carried out after the phase III clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of the children;
c. A parent or legal guardian of each child has given proxy consent;
d. The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors from the age of seven years up to the age of 18 years.;
e. Research should be conducted in settings in which the child and parent can obtain adequate medical and psychological support;
f. Interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child participant must be justified in relation to anticipated risks involved in the study and anticipated benefits to society;
g. The child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/ tested, provided the consent has been obtained from parents / guardian;
h. Interventions that are intended to provide therapeutic benefit are likely to beat least as advantageous to the individual child participant as any available alternative interventions;
i. The risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to be gained.

*3. Disasters*

Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

a. Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations.
b. Disaster-affected community participation before and during the research is essential and its representative or advocate must be identified.
c. Extra care must be taken to protect the privacy and confidentiality of participants and communities.
d. Protection must be ensured so that only minimal additional risk is imposed.
e. The research undertaken should provide direct or indirect benefits to the participants, the disaster-affected community or future disaster- affected population and *a priori* agreement should be reached on this, whenever possible, between the community and the researcher.
f. All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.
g. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

4. ***Other vulnerable /special groups***:

Effort may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.

a. Research on genetics should not lead to **racial inequalities or discrimination within family;** It should be kept in mind that within families each person is an individual who has the right to keep the information about himself or herself confidential. **Family members are not entitled to know each other's diagnosis.** Before revealing medical or

personal information about individuals to other family members, investigator must obtain consent of the individual to do so. While general principles of counselling require presence of both the spouses, necessary care must be taken not to end up in breaking the families

b. Persons who are **economically or socially disadvantaged** should not be used to benefit those who are better off than them;

c. Rights and welfare of **mentally challenged** and **mentally differently able persons** who are incapable of giving informed consent or those with behavioral disorders must be protected. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures. The entire consent process should be properly documented;

d. Adequate justification is required for the involvement of participants such as prisoners, students, subordinates, employees, service personnel etc. who have **reduced autonomy** as research participants, since the consent provided may be under duress or various other compelling reasons.

As different kinds of research (epidemiological studies, clinical trials, product development, behavioural and social science oriented research *etc.*) have their own particular scientific requirements and specific ethical challenges, the choice of study populations for each type of study should be justified in advance in scientific and ethical terms regardless of the place from where the study population is selected. Generally, early clinical phases of research, particularly of drugs, vaccines and devices, should be conducted in communities that are less vulnerable to harm or exploitation.

Address of the office of the Ethics Committee.

Office of IEC

DEPT. OF FORENSIC MEDICINE AND TOXICOLOGY

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## Name, address, qualification, organizational title, telephone number, fax number, e-mail, mailing address and brief profile of the Chairman.

| | | | |
|---|---|---|---|
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| 7. | Email ID | : | manjukathpal@satyam.net.in |
| 8. | Mailing Address | : | 9, Aditya Nagar, Indore (M.P.) |
| 9. | Brief profile of the Chairman: | | |

**ECR/1264/Sri Aurobindo/Inst/MP/2015/Re-Registration-2018**

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi – 110 002, India
Dated: 23/09/2019

To

**The Chairman**
**Institutional Ethics Committee,**
**Sri Aurobindo Medical College & P. G. Institute,**
**Indore-Ujjain State Highway, Bhanwrasla,**
**Tehsil Sanwer, Dist. Indore-453111,**
**Madhya Pradesh, India.**

**Sub: -** Ethics Committee Re-registration No. **ECR/748/Inst/MP/2015/RR-18** issued under Rule 122DD of the Drugs and Cosmetics Rules, 1945.

**Sir/Madam,**

Please refer to your application no. No/SAIMS/18 dated 28.06.2018 submitted to this Directorate for the Re-registration of Ethics Committee.

Based on the documents submitted by you, this office hereby Re-registers the **INSTITUTIONAL ETHICS COMMITTEE** situated at **SRI AUROBINDO MEDICAL COLLEGE & P. G. INSTITUTE, INDORE-UJJAIN STATE HIGHWAY, BHANWRASLA, TEHSIL SANWER, DIST. INDORE-453111, MADHYA PRADESH, INDIA** with Re-registration Number **ECR/748/Inst/MP/2015/RR-18** as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to the following conditions:

1. The re-registration is valid from 13-Jul-2018 to 12-Jul-2021, unless suspended or cancelled by the Central Licencing Authority.
2. The registration is subject to the conditions specified under the New Drugs & Clinical Trial Rules, 2019.
3. This certificate is issued to you on the basis of declaration/submission made by you.
4. No clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by an Ethics Committee in meeting unless at least five of its members as detailed below are present in the meeting, namely:-
   I. medical scientist (preferably a pharmacologist);
   II. clinician;
   III. legal expert;
   IV. social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person;
   V. lay person.
5. The Ethics Committee shall have a minimum of seven and maximum of fifteen members from medical, non- medical, scientific and non-scientific areas with at least,
   I. one lay person;
   II. one woman member;

III. one legal expert;
IV. one independent member from any other related field such as social scientist or representative of non- governmental voluntary agency or philosopher or ethicist or theologian.

6. One member of the Ethics Committee who is not affiliated with the institute or organization shall be the Chairperson, and shall be appointed by such institute or organization and one member who is affiliated with the institute or organization shall be appointed as Member Secretary of the Ethics Committee by such institute or organization.

7. The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted.

8. The committee shall include at least one member whose primary area of interest or specialisation is non- scientific and at least one member who is independent of the institution.

9. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

10. Members should be conversant with the provisions of New Drug and Clinical Trials Rules, 2019, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

11. The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.

12. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

13. The Ethics Committee may associate such experts who are not its members, in its deliberations but such experts shall not have voting rights, if any

14. No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the Clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest.

15. While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson. The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.

16. Any change in the membership or the constitution of the registered Ethics Committee shall be intimated in writing to the Central Licencing Authority within thirty working days.

17. The Ethics Committee shall review and accord approval to a Clinical trial, Bioavailability and Bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule of New Drugs and Clinical Trials Rules, 2019 and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, Good Clinical

Practices Guidelines and other applicable regulations.

18. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7: provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be: provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site.

19. Where a Bioavailability or Bioequivalence study centre does not have its own Ethics Committee, bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the Ethics Committee registered under rule 8:Provided that the approving Ethics Committee shall in such case be responsible for the study at the centre:Provided further that both the approving Ethics Committee and the centre, shall be located within the same city or within a radius of 50 kms of the bioavailability or bioequivalence study centre.

20. Ethics committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licencing Authority.

21. Ethics committee shall make, at appropriate intervals, an on-going review of the trials for which they have reviewed the protocol. Such a review may be based on the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites.

22. Where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyse the relevant documents pertaining to such event and forward its report to the Central Licencing Authority and comply with the provisions of Chapter VI, New Drugs and Clinical Trials Rules, 2019.

23. The Ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts wherever required, for deciding relatedness and quantum of compensation, as per condition no (22) mentioned above.

24. Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licencing Authority.

25. Ethics committee shall comply with the requirements or conditions in addition to the requirements specified under the Drugs & Cosmetics Act, 1940 and New Drugs and Clinical Trials Rues, 2019, as may be specified by the Central Licencing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.

26. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.

27. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.

**ECR/1264/Sri Aurobindo/Inst/MP/2015/Re-Registration-2018**

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Division)

FDA Bhawan, Kotla Road,
New Delhi – 110 002, India
Dated: 23/9/2019

**To**

**The Chairman**
**Institutional Ethics Committee,**
**Sri Aurobindo Medical College & P. G. Institute,**
**Indore-Ujjain State Highway, Bhanwrasla,**
**Tehsil Sanwer, Dist. Indore-453111,**
**Madhya Pradesh, India.**

**Sub:** Ethics Committee Re-registration No. **ECR/748/Inst/MP/2015/RR-18** issued under Rule 122DD of the Drugs & Cosmetics Rules, 1945.

**Sir/Madam,**

Please refer to your application submitted to this Directorate for the Re-registration of Ethics Committee.

Your Ethics Committee is hereby re-registered under Rule 122DD vide Re-registration No. **ECR/748/Inst/MP/2015/RR-18** with the following composition and all the condition mentioned under the Re-registration certificate issued to you.

| Sr. No. | Name of member | Qualification | Role/Designation in Ethics Committee |
|---|---|---|---|
| 1. | Dr. J. S. Kathpal | MBBS, MD (Neurology) | Chairman |
| 2. | Dr. Virendra Bhandari | MBBS, MD (Radiotherapy) | Member Secretary |
| 3. | Dr. Savita Inamdar | MBBS, DCH, MD (Pediatric) & FASE | Clinician |
| 4. | Dr. Sudhir Gokhale | MBBS, MD (Radiodiagnosis) | Clinician |
| 5. | Dr. Praveen K Arora | MBBS, MD (Forensic Medicine & Toxicology) | Clinician |
| 6. | Dr. Ajit Deshpande | MBBS, MD (PSM) | Clinician |
| 7. | Dr. Chhaya Goyal | MBBS, MD (Pharmacology) | Basic Medical Scientist |
| 8. | Dr. Amit V. Verma | MBBS, MD (Pathology) | Basic Medical Scientist |
| 9. | Mrs. Meena Chaphekar | LLB | Legal Expert |
| 10. | Dr. Usha Tiwari | MA, LLB & Ph.D | Lay Person |
| 11. | Mrs. Usha Bhandari | M.A. | Social Scientist |

Yours faithfully,

(Dr. V. G. Somani)
**Drugs Controller General (I) & Central Licensing Authority**

Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O
New Delhi-110002