STANDARD OPERATING PROCEDURE [SOP]

[Revision – IV, JUNE 2017]

I - AUTHORITY UNDER WHICH INSTITUTIONAL ETHICS COMMITTEE IS CONSTITUTED

The Chief Executive Officer (CEO), Charutar Arogya Mandal, will be the appointing authority under which Institutional Ethics Committee [IEC], HM Patel Centre for Medical Care and Education is constituted [HMPCMCE]. Currently, IEC, HMPCMCE is registered with ***Central Drugs Standard Control Organization [CDSCO] with registration no. ECR/ 331/ Inst/ GJ/ 2013/ RR-16, valid till 22nd May 2019*** and ***Office of Human Research Protections [OHRP], US Department of Health and Human Services [HHS] – Registration of an Institutional Review Board [IRB] with registration no. IORG0006830, valid till 31st March 2020***.

II - STATUS OF IEC WITH RESPECT TO ITS INDEPENDENCE IN FUNCTIONING AND DECISION MAKING

IEC [henceforth referred to as 'Committee'] will be multidisciplinary and multi-sectorial in composition. ***Independence and competence will be its two hallmarks.*** The Chairperson of the Committee will be from outside the institution to maintain its independence. The Member Secretary, to be appointed from amongst the members will conduct the business of the Committee. Other members will be a mix of medical/ non-medical scientific and non-scientific persons including lay person to reflect different viewpoints.

The Committee, will have as its member's individuals from other institutions or communities if required. There will be an adequate representation of age, gender, community, field etc. in the Committee to safeguard the interests and welfare of all sections of the community/ society. Members will be required to be aware of local, social and cultural norms, as this is the most important social control mechanism. If required, subject experts may be invited to offer their views [for example an anesthetist, may be included for trials related to anesthetic drugs or procedures]. Similarly, based on the requirement [s] of research area, for example HIV, genetic disorders etc. specific patient group [s] may also be represented in the Committee.

III - MANDATE OF THE COMMITTEE WITH PRINCIPAL INVESTIGATOR REQUIREMENTS

IEC will review and approve all types of research proposals involving human participants that conform to safeguard the dignity, rights, safety and well-being of all actual and potential research participants. **The goals of research, however important, will never be permitted to override the health and well-being of the research participants.** IEC will take care that all the cardinal principles of ethics viz. autonomy, beneficence, non - maleficence 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 Informed consent process, Risk benefit ratio, Distribution of burden and Provisions for appropriate compensations, wherever required. It will review the proposals before start of the study; once approved, will examine its compliance with all regulatory requirements, applicable guidelines and laws as updated with time and Monitor the research throughout the study until and after completion of the study.

The mandate of the IEC will be to review the research proposals:

1. Involving human participants/ biological specimens to be conducted on site at the Institutions of HMPCMCE by its staff members/ postgraduate students/ undergraduate students
2. From researchers of HMPCMCE involved either as Principal or Co-investigator at sites other than HMPCMCE
3. From staff members/ students of HMPCMCE as Co-investigator [proposed from outside the institution] but conducted within the institutions of HMPCMCE

For research involving human participants, eligibility criteria undertaken as Principal Investigator will be as follows:

1. Medical Faculty [includes medical and dental branches]
    - Short Current CV
    - Medical Registration Certificate
    - Copy of GCP Training Certificate
2. Non-Medical Faculty [including undergraduate students]
    - Short Current CV
    - Copy of GCP Training Certificate [preferable]
3. Principal Investigator [both medical as well as non- medical faculty]
    - At least 2 years' experience in Research as Co-investigator

- Copy of GCP Training Certificate

Eligibility of different investigators will be decided by the Committee depending upon the type of research proposal submitted

IV - SOP DEVELOPMENT, REVIEW AND REVISION PROCEDURE

The objective of SOP is to contribute to the effective functioning of the Institutional Ethics Committee of H. M. Patel Centre for Medical Care and Education, Karamsad [HMPCMCE, henceforth may be referred to as "Centre"] so that a quality and consistent ethical review mechanism for biomedical research is put in place for all proposals dealt by the Committee as prescribed by the Ethical Guidelines for Biomedical Research on Human Participants, ICMR [2006] and Schedule Y [Drugs and Cosmetic Rules, 1945 as amended from time to time].

The Standard Operating Procedures [SOP] will be reviewed periodically, not later than 2 years than the last version, based on changed requirements. Following procedure [s] will be followed for amendments/ revision:

- The amendment [s]/ revision will be in writing and circulated to all IEC members for their consideration.
- Views of the members will be discussed at the next scheduled meeting of the IEC, and a vote taken at that meeting.
- Any member unable to attend such a meeting may register his or her views in writing to the Member Secretary, in hard copy or on email.
- The amendment [s]/ revision will then be incorporated after the consensus by the full committee and approval by the Appointing Authority
- With every change in SOP, the same will be notified to the Registering Authority [CDSCO]

V - COMPOSITION OF IEC with PROCEDURES FOR NEW INDUCTION, RESIGNATION, REPLACEMENT AND REMOVAL OF MEMBERS

The members in the ethical committee will not be less than 7 [seven], maximum being 15. A minimum of five persons will be required to compose a quorum [this would include a clinician, basic medical scientist, legal expert, lay person and social worker].

A subcommittee [s] may be delegated to function independently by ensuring consistent

ethical framework for competent review and evaluation of ethical aspects of research proposals related to post graduate dissertations/ research projects involving undergraduate students/ regulatory requirements arising out of adverse [AE] or serious adverse events [SAE] as and when they occur. Similarly, expedited reviews may be delegated to panel of committee members as and when submitted and required. Every subcommittee will comply with quorum requirements, as required. ***[Annexure 1]***

The composition of the IEC will be as follows: -

i. Chairperson [mandatorily from outside the institution as per regulatory requirements as well as maintaining of its independence]
ii. Deputy Chairperson [to officiate in absence of Chairperson/ when Chairperson himself/ herself is an investigator or has any other declared conflict of interest]
iii. Member Secretary
iv. 5-15 members from different departments/ specialties/ disciplines etc.
    - Basic medical/ non-medical scientists
    - Clinicians from various departments
    - Legal expert
    - Social scientist/ representative of non-governmental voluntary agency
    - Philosopher/ ethicist/ theologian
    - Lay person from the community
    - Subject Expert [as invited member as and when need arises]

Efforts will be made to include individuals from other institutions or communities, have an adequate representation of age, gender, community, field etc. in the committee to safeguard the interests and welfare of all sections of the community/ society.

Members will be required to be aware of local, social and cultural norms, as this is an important social control mechanism. If required, subject experts may be invited to offer their views [for example an anesthetist, may be included for trials related to anesthetic drugs or procedures]. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Committee. List of current composition of Committee, along with their qualifications and roles, will always be updated on the Institutional Website. As per regulatory requirement, every change will be notified to CDSCO and updated on website too.

Terms of Appointment of members

1. The Appointing Authority will appoint the members in consultation with existing members of IEC. Members will be appointed based on their competencies and integrity and could be drawn from any public or private institute from anywhere in the country.
2. Once confirmed for appointment, the letter of appointment will include the date of appointment, length of tenure, an assurance from appointing authority that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as an IEC member.
3. At the time of joining, the member [s] will provide a copy of their Curriculum vitae, Medical Registration Certificate [wherever applicable], last qualification and Good Clinical Practices Training Certificate to the Committee Office.
4. Each new member will sign a confidentiality agreement upon appointment, stating that all matters of which he/she becomes aware during the course of his/her work on the IEC will be kept confidential and that any conflicts of interest, which exist or may arise during his/her tenure on the IEC, will be declared. A copy of the same will be retained by the member also. ***[Annexure 2]***
5. Upon appointment, members will be provided with the following documentation:
   - IEC Standard Operating Procedures (SOP)
   - Up to date list of members' names and contact information
   - Roles and responsibilities of each member [***Annexure 3]***
   - Any previous reports on the IEC's activities or relevant information
6. The duration of appointment will usually be for a period of 3 years. At the end of 3 years, as the case may be, the committee may be reconstituted or one third of the members be replaced.
7. A member can also be replaced:
   a. in the event of his/ her death
   b. in certain circumstances like for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member
   c. if he/ she fails to attend three consecutive meetings of the IEC, without prior intimation unless exceptional circumstances exist
   d. if a member fails to attend in at least two thirds of all scheduled IEC meetings in each year, barring exceptional circumstances.

The Chairman will notify the member of such lapse of membership in writing, recommending his/ her replacement to the Appointing Authority.

8. Any member can tender resignation [with one month's notice period or till suitable replacement is arranged] from the Committee with proper reasons to do so; the resignation will be sent to the Appointing Authority, routed through the Chairperson/ Deputy Chairperson [as per the circumstances].
9. In case of vacancy arising due to death/ resignation/ termination of a member, necessary efforts will be made to fill the vacancy of the former member as early as possible.
10. All members, old as well as new, will attend training sessions at regular intervals [new ones to attend within 1 year of appointment]. The costs associated with attendance at training and education sessions will be met by Center.
11. All the members will be well versed with their roles and responsibilities. The Member Secretary will arrange for evaluation of education and training of IEC members every six months through online questionnaire. This will be to ensure that all members are updated with the SOP, current regulatory guidelines and acceptable ethical standards.
12. Members may seek a leave of absence from the IEC for extended periods. Accordingly steps may be taken to fill the vacancy during leave of absence of the particular member, if need arises.

VI – INCOMES AND EXPENDITURES OF THE COMMITTEE

1. No fee will be charged for review of research proposals submitted by the investigators of the institution [HMPCMCE] for review EXCEPT for Industry Sponsored Clinical Trials.
    a. IEC fees for Clinical trials:
        - Rs. 50,000/- for initial review of each protocol
        - Rs. 5,000/- for review of each amendment
            - The revised fee structure will be applicable to new clinical trials submitted on or after 1st June 2017
2. Research projects initiated and submitted by investigators outside the institution [HMPCMCE] but to be conducted within the Centre will be accepted only after written permission granted by Institutional Research Group [on hard copy of the research proposal]

3. Research projects initiated and submitted by investigators outside the institution [HMPCMCE] and also to be conducted outside the institution will not be accepted for review.
4. Research proposal review fees will need to be deposited in favour of **"Charutar Arogya Mandal"** having PAN No: AAATC 1264G.
5. No member is expected to receive any remuneration, in either cash or kind, from any investigator or industry involved in the research proposal to be reviewed. Conflict [s] of interest, if any, will be declared prior to review as mentioned earlier and if required, depending upon the conflict of interest, will not be part of decision making during review process.
6. The Appointing Authority may provide for honorarium to member [s] of the Committee, as deemed necessary.
7. Expenses towards conduct of the meeting [s] will be borne by the Centre.
8. A statement of all income and expenditure [including honorarium] will be made available to IEC Office for records purposes at the end of each financial year by the Centre.

VII - ELEMENTS OF REVIEW

Each review will be based on Statement of General Principles as per ICMR Ethical Guidelines for Biomedical Research on Human Participant, 2006. If the case may be that these Guidelines are updated, then the same will be the basis of review, for the period new Guidelines are in vogue.

Any research using the human beings as participants will follow the principles given below –

1. **Principles of essentiality**, whereby the research entailing the use of human participants is considered to be absolutely essential after a due consideration of all alternatives in the light of the existing knowledge in the proposed area of research and after the proposed research has been duly vetted and considered by an appropriate and responsible body of persons who are external to the particular research and who, after careful consideration, come to the conclusion that the said research is necessary for the advancement of knowledge and for the benefit of all members of the human species and for the ecological and environmental wellbeing of the planet.

2. **Principles of voluntariness**, informed consent and community agreement whereby research participants are fully apprised of the research and the impact and risk of such research on the research participant and others; and whereby the research participants retain the right to abstain from further participation in the research irrespective of any legal or other obligation that may have been entered into by such human participants or someone on their behalf, subject to only minimal restitutive obligations of any advance consideration received and outstanding. Where any such research entails treating any community or group of persons as a research participant, these principles of voluntariness and informed consent will apply, mutatis mutandis, to the community as a whole and to each individual member who is the participant of the research or experiment. Where the human participant is incapable of giving consent and it is considered essential that research or experimentation be conducted on such Statement of General Principles in Biomedical Research Involving Human Participants a person incompetent to give consent, the principle of voluntariness and informed consent will continue to apply and such consent and voluntariness will be obtained and exercised on behalf of such research participants by someone who is empowered and under a duty to act on their behalf. The principles of informed consent and voluntariness are cardinal principles to be observed throughout the research and experiment, including its aftermath and applied use so that research participants are continually kept informed of any and all developments in so far as they affect them and others. However, without in any way undermining the cardinal importance of obtaining informed consent from any human participant involved in any research, the nature and form of the consent and the evidentiary requirements to prove that such consent was taken, will depend upon the degree and seriousness of the invasiveness into the concerned human participant's person and privacy, health and life generally, and, the overall purpose and the importance of the research. Ethics committee will decide on the form of consent to be taken or its waiver based on the degree of risk that may be involved.
3. **Principles of non-exploitation**, whereby as a general rule, research participants are remunerated for their involvement in the research or experiment; and, irrespective of the social and economic condition or status, or literacy or educational levels attained by the research participants kept fully apprised of all the dangers arising in and out of the research so that they can appreciate all the physical and psychological risks as well as

moral implications of the research whether to themselves or others, including those yet to be born. Such human participants should be selected so that the burdens and benefits of the research are distributed without arbitrariness, discrimination or caprice. Each research will include an in-built mechanism for compensation for the human participants either through insurance cover or any other appropriate means to cover all foreseeable and unforeseeable risks by providing for remedial action and comprehensive aftercare, including treatment during and after the research or experiment, in respect of any effect that the conduct of research or experimentation may have on the human participant and to ensure that immediate recompense and rehabilitative measures are taken in respect of all affected, if and when necessary.

4. **Principles of privacy and confidentiality**, whereby the identity and records of the human participants of the research or experiment are as far as possible kept confidential; and that no details about identity of said human participants, which would result in the disclosure of their identity, are disclosed without valid scientific and legal reasons which may be essential for the purposes of therapeutics or other interventions, without the specific consent in writing of the human participant concerned, or someone authorized on their behalf; and after ensuring that the said human participant does not suffer from any form of hardship, discrimination or stigmatization as a consequence of having participated in the research or experiment.
5. **Principles of precaution and risk minimization**, whereby due care and caution is taken at all stages of the research and experiment (from its inception as a research idea, its subsequent research design, the conduct of the research or experiment and its applicative use) to ensure that the research participant and those affected by it including community are put to the minimum risk, suffer from no known irreversible adverse effects, and generally, benefit from and by the research or experiment; and that requisite steps are taken to ensure that both professional and ethical reviews of the research are undertaken at appropriate stages so that further and specific guidelines are laid down, and necessary directions given, in respect of the conduct of the research or experiment.
6. **Principles of professional competence**, whereby the research is conducted at all times by competent and qualified persons who act with total integrity and impartiality and who have been made aware of, and are mindful of, preferably through training, the ethical considerations to be borne in mind in respect of such research or experiment.

7. **Principles of accountability and transparency**, whereby the research or experiment will be conducted in a fair, honest, impartial and transparent manner after full disclosure is made by those associated with the research or experiment of each aspect of their interest in the research, and any conflict of interest that may exist; and whereby, subject to the principles of privacy and confidentiality and the rights of the researcher, full and complete records of the research inclusive of data and notes are retained for such reasonable period as may be prescribed or considered necessary for the purposes of post-research monitoring, evaluation of the research, conducting further research (whether by the initial researcher or otherwise) and in order to make such records available for scrutiny by the appropriate legal and administrative authority, if necessary.
8. **Principles of the maximization of the public interest and of distributive justice**, whereby the research or experiment and its subsequent applicative use are conducted and used to benefit all human kind and not just those who are socially better off but also the least advantaged; and in particular, the research participants themselves and or the community from which they are drawn.
9. **Principles of institutional arrangements**, whereby there will be a duty on all persons connected with the research to ensure that all the procedures required to be complied with and all institutional arrangements required to be made in respect of the research and its subsequent use or application are duly made in a bonafide and transparent manner; and to take all appropriate steps to ensure that research reports, materials and data connected with the research are duly preserved and archived.
10. **Principles of public domain**, whereby the research and any further research, experimentation or evaluation in response to, and emanating from such research is brought into the public domain so that its results are generally made known through scientific and other publications subject to such rights as are available to the researcher and those associated with the research under the law in force at that time.
11. **Principles of totality of responsibility**, whereby the professional and moral responsibility, for the due observance of all the principles, guidelines or prescriptions laid down generally or in respect of the research or experiment in question, devolves on all those directly or indirectly connected with the research or experiment including the researchers, those responsible for funding or contributing to the funding of the research, the institution or institutions where the research is conducted and the various persons,

groups or undertakings who sponsor, use or derive benefit from the research, market the product (if any) or prescribe its use so that, inter alia, the effect of the research or experiment is duly monitored and constantly subject to review and remedial action at all stages of the research and experiment and its future use.

12. **Principles of compliance**, whereby, there is a general and positive duty on all persons, conducting, associated or connected with any research entailing the use of a human participant to ensure that both the letter and the spirit of these guidelines, as well as any other norms, directions and guidelines which have been specifically laid down or prescribed and which are applicable for that area of research or experimentation, are scrupulously observed and duly complied with.]

During the review process, the IEC will consider the following elements of a given research proposal:

a. Scientific design and conduct of the study
b. Examination of predictable risks/harms & potential benefits with communication to the study participants
c. Recruitment strategies
d. Procedure for independent selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details etc.
e. Protection of subject rights and responsibilities
f. Management of research related injuries, serious adverse events
g. Compensation provisions
h. Justification for placebo in control arm, if any
i. Availability of products after the study, if applicable
j. Informed Consent Process [includes participant information sheet, informed consent form in local languages, along with AV recording protocols [where necessary]
k. Protection of privacy and confidentiality
l. Involvement of the community, wherever required
m. Plans for data analysis and reporting
n. Adherence to all regulatory requirements and applicable guidelines changing from time to time [including CDSCO, GOI, ICMR etc.]
o. Competence of investigators, research and supporting staff
p. Facilities and infrastructure of study sites

q. Criteria for withdrawal of patients, suspending or terminating the study
r. Mechanism declared for trial participant to contact IEC, if need arises
s. Justification for waiver of informed consent
t. Protection of vulnerable population [as stated later]

[Law of the land will be given absolute preference to any prevailing national or international guidelines while reviewing any research proposal]

Protection of vulnerable population

1. Vulnerability

- The Council for International Organizations of Medical Sciences (CIOMS) new guidelines [2016] no longer label entire classes of individuals as vulnerable. CIOMS more clearly emphasizes that unless a good scientific reason justifies their exclusion, children and persons who are incapable of giving informed consent must be included in research investigations, provided that appropriate safeguards are in place. Ethics Committees should evaluate the specific context-dependent characteristics that may place study participants at increased risk of being harmed or wronged.
- Just as the definition of vulnerability is context dependent, so is the delineation of special protections. Ethics Committees are expected to devise special protections for groups considered to be vulnerable, including allowing for no more than minimal risks for research procedures that offer no potential individual benefits for participants, or requiring that the research be carried out only when it targets conditions that affect these groups. Ethics committees are expected now to enable the participation of vulnerable individuals by protecting their rights and interests through special safeguards and protections.
- Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests.
- Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable (WHO).

2. Responsibility

- EC members will identify study proposals including vulnerable participants (population) and ensure that these are considered for full board review.
- EC will ensure that measures for safeguarding rights and interests of vulnerable participants are taken care of in the study proposal. They will ensure that the vulnerable population is not exploited and guide the investigators to design protocols and describe the process of informed consent in such a manner that this will be done.
- EC will see whether the inclusion of vulnerable populations in the study is justifiable or the population is just being exploited to generate clinical data. In such cases, the risk benefit analysis needs to be done critically.
- 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:
  - Research on genetics should not lead to racial inequalities.
  - Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them.
  - Rights and welfare of mentally challenged and differently abled persons who are incapable of giving informed consent or those with behavioral disorders must be protected. Appropriate proxy consent from the legally acceptable representative 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.
  - 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.
  - Persons, who are terminally ill, have incurable disease and mental illness.
- Before undertaking research/trial in children the investigator must ensure that:
  - Children will not be involved in research that could be carried out equally well with adults.

- 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.
- A parent or legally acceptable representative of each child has given proxy consent.
- 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 7 years up to the age of 18 years.
- Research should be conducted in settings in which the child and parent can obtain adequate medical and psychological support.
- 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.
- 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.
- Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternative interventions.
- 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.

➢ 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 fetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable participants.

- 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 fetal 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.
- Only consent of the women should be mandatory and no proxy consent/ refusal allowed.
- 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.
- Research related to pre-natal diagnostic techniques:
  - In pregnant women such research should be limited to detect the fetal abnormalities or genetic disorders as per the Pre Conception and Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the fetus.

VIII – FUNCTIONING OF THE COMMITTEE

1. The IEC will meet on a regular basis, preferably each month but not later than 2 months from previous meeting. Beginning each year [1st January], IEC will prepare a tentative meeting calendar and try to adhere to it [barring unforeseen circumstances/ incomplete quorum]. The tentative calendar will be displayed on Institutional Website. Based on the calendar, the Member Secretary will announce the date of forthcoming IEC meeting along with closing date of submission of proposals online.
2. The Committee uses eEC Online Software [Since 1st April 2017; www.iecmanager.org/institution/15] for submission and review of research proposals. Upon such announcement, the potential Principal Investigators [henceforth referred to

as PI] will submit their research proposal in the IEC format ***[Annexure 4, 4.1 & 5]*** with signatures of all investigators as well as concerned Head [s] of Department [wherein the research project will be executed] in 1 [one] hard copy to the IEC Office requiring Full Committee/ Board Review.

3. For non-regulated projects, an investigator cannot undertake any research project as Principal Investigator for more than 3 projects and as Co-Investigator for more than 3 projects at any given time. This would exclude the Postgraduate dissertations.
4. For regulated projects, CDSCO directives will be followed by the committee. As on date, it has been left on EC to take a decision with regards to whether a Principal Investigator can undertake more than 3 Regulated Clinical Trials at a given material time.
5. An undergraduate student shall not be a part of more than 2 [two] research project at a given time.
6. All investigators need to declare at the time of submission of their new project with regards to their on-going approved projects and their status. Without submission of this data, no new research proposal will be taken for review.
7. All investigators are required to declare their specific role in that respective project at the time of submission of new research project
8. Following acceptance at the IEC Office, the PI will then upload the research project in the eEC Software. IEC Administrator/ Co-ordinator will then delegate all new arrivals to the Member Secretary, who in turn will delegate review of the new proposals to members of IEC.
9. After review, members will pass on their individual comments/ suggestions back to Member Secretary, who will compile all the comments/ suggestions [if needed] and pass it on to the PI for compliance.
10. PI who have been through with initial submission and satisfactory compliance to suggestions preferably 1 week prior to scheduled meeting may be called for the meeting and agenda prepared accordingly.
11. Routinely, the closing dates for receiving applications for Full Committee/ Board Review will be no earlier than 10 – 14 days prior to each IEC meeting. Care will also be taken that investigators get the announcement at least 10 days prior to closing date of submission.
12. A checklist as per the software requirements will be made available to the investigators ***[Annexure 7]***.

13. All annexures pertaining to submission of research projects will be made available on Institutional Website.

IX. CONDUCT OF FULL COMMITTEE/ BOARD MEETING

1. Once agenda is prepared, it will be intimated to the investigators and IEC members online/ through emails. It will include the time as well as place for the meeting. No proposal will be considered for approval unless the meeting is attended by Principal investigator/ Co-investigator.
2. Members who are unable to attend a meeting can contribute prior to the meeting through online comments/ suggestions to the Member Secretary. If required, minutes of meeting may include such written comments.
3. Meetings will be scheduled for an allocated time. If the issues have not been completed within the allocated time, then the IEC may either continue the meeting until all agenda items have been considered or schedule an additional meeting. If an additional meeting is called for, then the meeting will be tried to be held within 14 working days.
4. The IEC meetings will be conducted in a way to ensure confidentiality and open discussion between members and the investigator [s].
5. A quorum has to be mandatorily complete in order for the IEC to reach a final decision on any agenda item as stated earlier for Pharma/ Government Sponsored Clinical Trials. For researches, non-regulatory in nature, minimum 7 members need to complete a quorum with no binding for legal expert/ lay person/ social scientist to be mandatorily present.
6. The Chairperson/ Deputy Chairperson will have authority to cancel a scheduled meeting, if a quorum cannot be achieved. Should this occur the IEC will try to convene next meeting within 14 working days of the cancelled meeting to ensure that all agenda items are reviewed in time.
7. In cases of declared conflict of interest [of member/ investigator], the IEC will determine whether a conflict of interest does exist or not, and if it exists, will require the member to withdraw from the meeting until the IEC's consideration of the relevant matter has been completed. The concerned member [s] will not be permitted to adjudicate on the research or be part of the decision making process. ***[Annexure 2.1]***

8. All such declarations of conflict of interest and the absence of the member concerned will be noted in minutes of the meeting.
9. All suggestions will be communicated to the members in writing. Compliance arising out of them will be reviewed by panel of committee members, as per discretion of Member Secretary, before grant of approval.
10. For amendments to approved proposals [non regulatory in nature], the Member Secretary, as per his discretion may delegate it for review to one or more Committee member [s] without convening a full board meeting.
11. All communications by the IEC Office, to all the Stake holders, will be either in writing/ online/ through emails in the pre-made formats ***[as per the Annexures]***

X. REPORTING AND HANDLING OF SERIOUS ADVERSE EVENTS

A Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (SADR) refers to an adverse event (AE) or adverse drug reaction (ADR) that is associated with death, inpatient hospitalization (in case the study was being conducted on out-patients), prolongation of hospitalization (in case the study was being conducted on in-patients), persistent or significant disability or incapacity, a congenital anomaly or birth defect, or is otherwise life threatening.

Any injury or death of the subject occurring in any approved research project [including clinical trial] due to following reasons will be considered as clinical trial related injury or death and the subject or his/ her nominee (s), as the case may be, are entitled for financial compensation for such injury or death *[7 criteria as mentioned under Rule 122 DAB and Appendix XII of Schedule Y to the Drugs and Cosmetics Rules]*:

a. adverse effect of the investigational product [s]
b. violation of the approved protocol, scientific misconduct or negligence by Sponsor or his representative or the investigator
c. failure of investigational product to provide intended therapeutic effect
d. use of placebo in a placebo-controlled trial
e. adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol
f. for injury to a child in-utero because of the participation of the parent in clinical trial
g. any clinical trial procedures involved in the study

Reporting of a SAE:

1. Principal Investigator will, within 24 hours, report [by telephone/ email/ in hard copy to the Chairperson, IEC] all Serious Adverse Events in clinical trials to the IEC in accordance with the reporting conditions required by Schedule Y, Drugs and Cosmetic Rules, 1945 [Subparagraph (3) relating to the 'Responsibilities of the Investigator (s)] as per Appendix XI of the said rules.
2. In case there is a holiday/ weekend on the day of electronic reporting, PI will report the same in hard copy on next 1st working day.
3. The Sponsor and Investigator are expected to forward the reports on all the serious adverse event [s], after analysis to the Ethics Committee and Head of the Institution [CAM], along with a copy of the report to the Licensing Authority within 14 calendar days after occurrence of the serious adverse event [s] of death
4. The same [serious adverse events and the response to those events] will be included in the periodic and final reports for the project also.

IEC Analysis, Causality Assessment & Justification and Opinion:

1. In case of serious adverse event occurring to the clinical trial subject, the IEC will convene either a Full Committee/ Board Meeting or SAE Sub-Committee [if it exists] meeting within 30 days of date of reporting by PI.
2. As stated earlier, to complete a quorum, minimum of 5 [five] members [as per Schedule Y] will be required for the meeting to review the SAE.
3. The reported SAE will be reviewed in presence of PI or Co-Investigator [Co-I]. [If none of the investigator [s] attends the meeting, the Committee shall review the matter based on available documents. If deemed necessary, the Committee may approach the participant or his/ her legally acceptable representative, before arriving at any decision. In such an event, the decision of the Committee shall be binding to the PI and Sponsor].
4. Necessary document [s] will be reviewed and investigator may even be asked to submit a copy of relevant documents too.
5. The Committee will ensure during the review that trial participant has been provided with adequate medical care as per applicable rules and regulations. For the same, it may even direct the Sponsor to bear the costs of the medical treatment of reported SAE till it is proved that current medical condition has no relation the trial in question [as per current CDSCO Regulations].

6. Causality assessment & justification will be done using WHO/ Naranjo Causality Assessment Tool. ***[Annexures 12, 13]***
7. As usual, minutes of meeting will be prepared by Member Secretary [with all required elements as stated above and additional SAE reporting requirements] and got approved by the SAE Sub-Committee Members.
8. Once minutes approved, SAE Sub-Committee Report will be prepared and forwarded to CDSCO with its recommendations so as to reach it by mail/ post within 30 days of reporting of the SAE. ***[Annexure 14]***
    a. The report will include copy of Appendix XI, Duly Analysis Report by Investigator, Sponsor's Report, WHO/ Naranjo Causality Assessment Tool [with signatures of attending members] and Minutes of Full Committee/ Board or SAE Sub-Committee Meeting wherein the SAE was reviewed.
    b. The report will also include a request to Expert Committee [for review of SAE at CDSCO] to forward a copy of its decision for record purposes.
    c. In case the Expert Committee decides to award compensation to the study participant/ legally acceptable representative, the committee will request to be provided an acknowledgement of disbursement of compensation for record purposes.
8. The compensation amount [if deemed necessary] will be determined based on the guidelines provided by CDSCO as available at:
    a. Formula to determine the quantum of compensation in case of clinical trial related serious adverse events [SAE] of deaths occurring during clinical trials; http://www.cdsco.nic.in/writereaddata/formula2013SAE.pdf ***[Annexure 15]***
    b. Formula to determine the quantum of compensation in case of clinical trial related injury [other than death]; http://www.cdsco.nic.in/writereaddata/ORDER%20and%20Formula%20to%20Determine%20the%20quantum%20of%20compensation%20in%20the%20cases%20of%20Clinical%20Trial%20related%20serious%20Adverse%20Events(SAEs)%20of%20Injury%20other%20than%20Death.pdf ***[Annexure 16]***

XI. PREPARATION OF MINUTES OF MEETING [including SAE Sub-Committee MEETING]

1. During the Full Committee/ Board meeting, all ethical issues with research protocol related issues raised and needed to be complied will be discussed with the respective investigator [s].
2. It will be the duty of Member Secretary to prepare and maintain minutes of all meetings of the IEC. The format will include: Attendance of members, brief agenda, notification of approval of minutes of previous meeting, Suggestions for new proposals/ amendments, conflicts of interest, if any, monitoring reports, if any and any other issue [e.g. expedited reviews, subcommittee minutes etc.], if required.
3. The minutes will also include the recording of decisions taken by the IEC as well as a summary of relevant discussion. This will include reference to views expressed by absent members also, if necessary. In relation to the review of new applications or amendments, the minutes will record a summary of the main ethical issues considered [if any apart from expected elements of review], including any requests for additional information, clarification or modification of the project etc.
4. While recording a decision made by the IEC after voting [in a particular case], any significant minority views (i.e. 2 or more members) if any, will also be noted in the minutes. To encourage free and open discussion and to emphasis the collegiate character of the IEC, particular views will not attribute to particular individuals in the minutes, except in circumstances where a member seeks to have his/her opinions or objections recorded.
5. Declarations of conflicts of interest by any member of the IEC and the absence of the member concerned during the IEC consideration of the relevant application will be included in the minutes too.
6. The minutes will be circulated to all, following the respective meeting on email and any suggestions/ corrections sought. Corrections/ suggestions [if any by members] will be incorporated and approved by Chairperson/ Deputy Chairperson. The same will be officially read out in subsequent meeting for approval by all the members; which again will be recorded in the minutes of that particular meeting.
7. The original copy of each meeting's minutes will be retained in a confidential 'Minutes of meeting' file at the IEC Office.

XII. COMMUNICATION OF DECISIONS OF THE INSTITUTIONAL ETHICS COMMITTEE

1. Following online review by members of IEC, a query letter prior to the scheduled meeting may be sent online through eEC Software, where needed.
2. After the review meeting, The IEC will report in writing to the Principal Investigator (PI) the decision of the committee after the minutes are approved by all members and signed by the Chairperson/ Deputy Chairperson. A copy of the same will also be sent through eEC Software too.
3. If the IEC determines that further information, clarification or modification is required for the consideration of a project, the correspondence to the PI will clearly articulate the reasons for this determination, and clearly set out the information that is required.
4. For non-regulated trials, if the requested information is not received from the applicant within 1 month of issue of suggestion letter, the project may be dismissed and the applicant will be required to resubmit the project at a later date as fresh application.
5. For regulated trials, if the requested information is not received from the applicant within 3 months of issue of suggestion letter, the project may be dismissed and the applicant will be required to resubmit the project at a later date as fresh application.
6. Once a compliance to suggestions of reviewed proposals is received, it will be the discretion of the Member Secretary to get the re-submission reviewed by one/ more members of IEC without convening a Full Committee/ Board Meeting ***[Annexure 8]***
7. After receipt of the comments of the IEC members, depending upon them, approval may be granted to the concerned research project.
8. In all cases, IEC will notify the PI of the ethical approval of a project only when all outstanding requests for further information, clarification or modification have been satisfactorily resolved. Ethical approval letter will be issued in Schedule Y Format, Appendix VIII [2] ***[Annexure 9]***
9. If the IEC determines that a project is ethically unacceptable or the approval needs to be revoked, the notification of the IEC's decision will include the grounds for the same while communicating to the PI, in hard copy as well as soft copy.
10. The status of the projects will be regularly updated in the IEC's data of received and reviewed applications for record purposes.
11. Communication from IEC to Investigator regarding decision on the proposal will

ordinarily be done within 15 working days after review of the application in the full committee/ in cases of Exempt from Full Committee/ in cases of Expedite Reviews/ in cases of case report or series.

XIII. EXEMPT from FULL COMMITTEE REVIEW AND EXPEDITED REVIEW PROCESS

Apart from research proposals taken for Full Committee/ Board Meeting, investigator [s] can submit their research projects/ case reports/ case series any time to the IEC, in the same way as mentioned above, with justification as to why their research project should be considered for exempt review.

Project [s] will be considered eligible for Exempt from Full Committee Ethical Review where they:

a. Involve the use of existing collections of data or records, where there is no contact with any participant [declaring maintenance of privacy and confidentiality]
b. Research is on data available in the public domain
c. Research is on anonymized data derived from participants during course of a routine standard practice
d. Research has less than minimal risk to participants
e. Involve reporting of an interesting case [s], declaring maintenance of privacy and confidentiality, where informed consent is not attainable from the patient/ legally acceptable representative [also if informed consent is available]

Few examples that may be eligible for exemption from review include:

- Case report [s] or series ***[Annexure 6, 6.1]***
- Retrospective data analysis [s]
- Audits of educational practices
- Research on microbes cultured in the laboratory without identifiers

Upon submission of such a proposal [as stated above], IEC will review and decide whether a project is eligible for exempt from full committee ethical review. The Member Secretary will provide written communication to the PI as to whether a project is exempt from full committee ethical review by the IEC or not. If not, it will be considered for review by Full Committee/ Board in subsequent meeting [s].

Project [s] will be considered eligible for Expedite Review where they involve:

a. Minor amendments and extensions of approved protocols
b. Urgent amendments to approved protocols for safety reasons
c. Urgent proposal of national interest
d. Research on interventions in emergency situations i.e. epidemic
e. Research on Disaster management

Few examples that may be eligible for Expedited Review:

- Revised proposal with minor modifications previously approved through full review by the IEC
  - Change in the name, address of sponsor
  - Change in contact details of Principal Investigator, and Member- Secretary, IEC
  - Request for change in Principal Investigator, Co-Investigator, change in any member involved in the research etc.
  - Minor corrections in budget
  - Other administrative changes in the investigator brochure, informed consent document etc.

1. Expedited Review [s] of research projects may be undertaken between scheduled meetings at the discretion of the Member Secretary, depending upon the need. The Member Secretary will be free to seek advice from other IEC members or suitably qualified experts, as appropriate [usually 2-3 members/ experts], before reaching a decision. Any research that is deemed to have potential risk/ raises ethical issue after such expedite review may be slotted for review in the next full committee meeting and the decision of the same will be communicated to the investigator, in hard as well as soft copy.
2. Methodology for conduct of the meeting, review procedure, noting of minutes and communication with the PI will remain same as stated above. The decision and minutes of this review will be noted down for ratification at the next IEC meeting.
3. Any research with the potential for physical or psychological harm to the trial participant will generally be not considered for expedited review. This includes, and is not limited to, regulated clinical trials, research involving invasive physical procedures and research exploring sensitive personal or cultural issues.
4. Where any research involves a departure from the ethical principles of integrity, respect for persons, beneficence and justice, the protocol will be considered in the Full Committee/

Board Meeting and not dealt with Expedited Review.

XIV. PROCEDURE FOR AMENDMENTS

1. Any proposed changes to approved projects will require to be reported by the PI to the IEC for review. Such requests will outline the nature of the proposed changes, reasons for the changes, and an assessment of any ethical implications arising from the request on the conduct of the research. All amended documents [submitted in hard as well as online] will have the changes highlighted and contain revised version numbers and dates.
2. Expedited Review of requests for minor amendments and urgent amendments to approved protocols for safety reasons may be undertaken by the Member Secretary between scheduled meetings at the discretion of the Chairperson [as above], which will be ratified at the next IEC meeting.
3. All other requests for amendments will be reviewed by the IEC at its next scheduled Full Committee/ Board meeting, provided the request has been received by the Member Secretary by the agenda closing date.
4. The decision of the IEC will be communicated in writing to the PI, advising whether the proposed amendment and/or request for extension has been given ethical approval within 15 working days of the meeting at which the request was considered [this may be the Full Committee meeting or Expedited Review Meeting].
5. Notification of the approval of amendments and extensions will be conveyed in writing in the standard format as per Schedule Y [as stated above].
6. If the IEC determines that further information, clarification or modification is required for the consideration of the request for amendment or extension, the correspondence to the investigator will clearly articulate the reasons for this determination, and will clearly set out the information that is required.
7. All received and approved requests for amendments and extensions will be recorded, and the status of the project updated in the IEC's data of received and reviewed applications.

XV. CONCERNS AND COMPLAINTS ABOUT THE CONDUCT OF A PROJECT

Reporting

1. The IEC requires, as a condition of approval of each project, that the researchers immediately report to it any concerns or complaints received with regards to the ongoing approved research project.
2. The Member Secretary will be the nominated person to receive concerns and complaints from participants in research or members of the public about the conduct of projects approved by the IEC. He will be responsible for obtaining, in writing, the grounds of the concern or complaint that will be notified to the Chairperson, as soon as possible.
3. Upon receipt of such complaint, Member Secretary will acknowledge to the complainant outlining the mechanism for investigating the concern or complaint.
4. In case where deviation/ violation from or changes to the protocol [s] occur, they are to be reported by the PI within 15 days of such deviation/ violation.

   A protocol deviation occurs when the activities during a study diverge from the IRB - approved protocol; a variance from protocol

   Examples of protocol deviations:

   - Vital signs obtained prior to informed consent
   - Weighing participant with shoes on
   - Urine dipstick is completed, but not sent for formal U/A
   - Targeted physical exam documented instead of complete PE
   - Conjugated bilirubin, part of the protocol, is left off the lab request form, but total bilirubin was drawn and is normal

   A protocol violation occurs when there is divergence from the IRB - approved protocol (a deviation) that also: – reduces the quality or completeness of the data impacts a subject's safety, rights or welfare – affects the scientific integrity

   Examples of Protocol Violations

   - Inadequate informed consent
   - Enrolment of subjects not meeting the inclusion /exclusion criteria
   - Initiation of study procedure prior to completion of informed consent
   - Unreported SAE's
   - Improper breaking of the blinding of the study
   - Use of prohibited medication

- Incorrect or missing tests
- Mishandled samples
- Multiple visits missed or outside permissible windows
- Inadequate record – keeping
- Intentional deviation from the protocol, GCP or regulations by study personnel in a non - emergency setting
- Repeated noncompliance by the subject
- Repeated deviations of the same nature
- Falsification

5. On the other hand, if any deviation is needed to be implemented without prior written approval of Ethics Committee [as in to eliminate immediate hazards to the trial subject (s) or when change (s) involve (s) only logistic or administrative aspects of the trial], they should be notified to the Ethics Committee within 30 days of such deviation/ change in protocol [time limits subject to change as per the latest regulations].
6. All such deviations/ violations reported will clearly indicate the effect of such deviation has any adverse effect on participant safety or not?

Investigation

1. The Chairperson will examine the concern or complaint and determine whether the concern or complaint warrants a further investigation. Where there is to be no further investigation deemed necessary, the Chairperson will inform the complainant, through Member Secretary in writing about the same. All the members will be intimated of such episodes in the next Full Committee/ Board Meeting and included in the Minutes of the Meeting too.
2. Where the Chairperson determines that the concern or complaint warrants a further investigation, he/ she will notify the Head of the Institution who may then convene a Review Committee to investigate and determine the consequences. Clarification or answer from the Principal Investigator will be sought on the raised issue.
3. The Member Secretary will then issue a letter of notification to the PI of any concern or complaint about a project received by the IEC outlining the mechanism for investigating the concern or complaint. Where the complaint concerns the conduct of the any other person, the review Committee will also notify that person too.
4. The Review Committee will immediately go for an investigation into the concern or

complaint. The investigation will not take longer than 2 weeks from the time of notification for the concern or complaint to be addressed, unless exceptional circumstances exist.

5. The Review Committee will give the complainant and the PI an opportunity to make submissions. Where the complaint concerns the conduct of any other person, the Review Committee will also provide that person with an opportunity to make submissions.
6. The Review Committee may seek any other information it requires and may access any documents relating to the project, interview other people, and seek internal and external expert advice, as it sees fit.

Consequences

1. If the Review Committee will meet in person and if it is satisfied that the concern or complaint is justified, it will determine the consequences by considering the following matters:
   - Severity of the matter
   - Sensitivity of any information concerned including the amount and type of information and the level of identifiability
   - Whether any breach of the approved protocol, which may be established, was inadvertent, negligent or unintentional
2. The possible consequences will include the following:
   - Noting on the file of the occurrence of the matter;
   - Increased monitoring of the project;
   - Counseling on security practices;
   - Amendments to the approved protocol;
   - Revoking of approval for the project
   - Reporting the individuals responsible for any breach of ethics to the Head of the Institute, with a complaint of misconduct in the execution of the project
3. The Chairman, Review Committee will notify the institution, the PI and any other person for whom there is an individual consequence to the outcome of the investigation, the consequences in writing.
4. The Chairman, Review Committee will also notify the Ethics Committee and any other Institutional IECs concerned with the project to the outcome of the investigation and the

consequences in writing.

5. The IEC will then re-review the ethical approval of any project in the light of the outcome of the investigation of any breach of ethics or justifiable complaint and will notify the responsible institution and the PI, if ethical approval for the project is to be revoked.
6. The Chairman, Review Committee will also send a written report of the outcome of the investigation and the consequences to the complainant in writing.
7. In cases of protocol deviation/ violation reported by the PI, they will be reviewed in the next Full Committee/ Board Meeting, unless any such deviation/ violation has a risk on participant wellbeing/ safety.
8. In case of a risk on participant wellbeing/ safety, the Member Secretary will convene an Expedite Review Meeting to deal with the reported matter. Procedure for conduct of meeting, review, minutes as well as communication with the PI will remain the same as above.

XVI. MONITORING OF APPROVED PROJECTS

1. The Committee will monitor approved projects to ensure compliance with the approved protocol. In doing so it can call for and discuss information on any relevant aspect (s) of the project with the investigator (s) at any time. In particular, the Committee may require investigators to provide interim reports on stipulated dates and a final report at completion of the study. Continuing approval of the research is subject to the PI submitting an interim report by the stipulated date [if required].
2. The Committee will require the following information in the report:
   - Progress to date, publications or outcome in the case of completed research
   - Maintenance and security of records and data
   - Compliance with the approved protocol
   - Compliance with any conditions of approval
   - Changes to the protocol or conduct of the research
   - Changes to the personnel of the PI /other investigators and
   - Serious Adverse events or complaints relating to the project
3. The Committee may adopt any additional appropriate mechanism (s) for monitoring, as deemed necessary, such as: random inspections of research sites, data and signed

consent forms; interview, with the prior consent, of research participants etc. to ensure:

a. Participant's right, safety and wellbeing in the project
b. Adequacy and continuity of the informed consent process
c. Any cause assessment needed for non-compliance [s]
d. Opportunities are identified for any improvements and their appropriate actions

4. For the same, the Committee may identify few members to oversee respective projects. These members, after their visit, will be required to submit their report.

[Annexure 10, 10.1]

5. The Committee will require, as a condition of approval of each project, that investigators immediately report anything which might warrant review of ethical approval of the protocol, including:
   - proposed changes in the protocol
   - any unforeseen events that might affect continued ethical acceptability of the project new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the trial, or which may indicate the need for amendments to the trial protocol.
6. The Committee also requires, as a condition of approval of each project, that investigators inform the IEC, giving reasons, if the research project is discontinued before the expected date of completion, and that the investigators comply with the approved protocol.
6. Where the Committee is satisfied that circumstances have arisen such that a research project is not being or cannot be conducted in accordance with the approved protocol, it may withdraw its approval. In such circumstances, the Committee will inform the PI and the Head of the Institute, the research project to be discontinued, suspended, or any other necessary steps to be taken.
7. In determining the frequency and type of monitoring required for approved projects, the Committee will give consideration to the degree of risk to participants in the research project, depending upon individual project.
8. At the end of each financial year, before preparing its report to the Appointing Authority, the Committee will require all investigator [s], whose projects have been approved in the preceding year, to declare to the Committee, in writing the status of their ongoing research projects.

XVII. RECORD KEEPING

1. The Committee will have a designated Office with preferably a separate record room for archiving of its records.
2. Co-ordinator, appointed for the Committee, will be responsible for the official works of the Committee, including Communication with the stakeholders.
3. The Office will maintain register of all projects/ requests submitted along with a separate register of all its Communications with stake holders.
4. It will preferably include:
    - Protocol number [as per the inward number generated on submission of application along with date]
    - Names of PI
    - Title of the project
    - Ethical approval or recommendations for modifications or rejections with date
    - Approval or otherwise of any changes to the project proposed by the researcher
    - The terms and conditions if any, with approval of the project
    - Whether approval was by scheduled Full Committee review or Expedited review or review by Subcommittee
    - Action taken by the IEC, while monitoring the conduct of the research
5. With the use of online software for submission, review, communication and decision of the Committee, the Co-ordinator will function as IEC admin to regulate the use of online software for Committee purposes.
6. Apart from online submissions, a hard copy of all the research projects [including amendments, SAE reports etc.] will be maintained by the Committee Office.
7. The physical records will contain a hard copy of the application, any relevant correspondence between the applicant, other stake holders and the Committee, other material used to inform potential research participants and all approved documents.
3. All documents of the IEC, including applications, membership, minutes of meeting and correspondence will be kept confidential and in accordance with Schedule Y and ICMR guidelines.
4. To ensure confidentiality, all documents provided to IEC members, which are no longer

required, are to be disposed of in a secure manner, such as shredding or incineration.

5. All relevant records pertaining to research projects will be held for at least a period of 5 years, from the time of closure of research project to allow for future reference and in compliance with regulatory requirements.
6. Access to the records will be available only to Member Secretary and the Co-ordinator of the Committee.
7. A register/ file will be maintained in the Office, IEC that will document the access to the records of the Committee along with name of person, time, date and reason for the same [whenever needed].
8. All efforts will be made to keep the records under lock and key for maintaining security and confidentiality.

XVIII. PERIODIC SELF ASSESSMENTS

The Committee will undertake periodic self-assessment by getting an Internal Audit done by Quality Improvement Group, once a year in accordance with NABH Guidelines. Report of the same will be furnished to the Registering Authority at the time of renewal of IEC Registration. Based on the assessment report, corrective measures [if any suggested] will be implemented within 30 days, depending upon their feasibility. In case the recommendations cannot be implemented, a report on the same will be submitted to the Appointing Authority, declaring the reasons for the same.

XIX. IEC ANNUAL REPORT

The Committee will provide an annual report on its progress for the financial year to the Appointing Authority [Head of the Institution], which will include:

- Membership changes
- Number of meetings
- Number of projects reviewed, approved, pending review, pending approval (non-compliance by researcher to modifications suggested) and rejected
- General issues raised
- Yearly audit of the income and expenditure

BIBLIOGRAPHY

1. Operational Guidelines for Ethics Committees That Review Biomedical Research. Available at http://www.who.int/tdr/publications/documents/ethics.pdf
2. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6 (R1). Current Step 4 Version. Dated 10 June 1996. Available at http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf
3. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6 (R2). Current Step 4 Version. Dated 09 November 2016. Available at http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf
4. Ethical Guidelines for Biomedical Research on Human Participants, ICMR; New Delhi, 2006. Available at http://icmr.nic.in/ethical_guidelines.pdf
5. Schedule Y. The Drugs and Cosmetics Rules, 1945 [as amended up to 15th August, 2013]. Available at http://www.mohfw.gov.in/showfile.php?lid=3036
6. Preparation of Standard Operating Procedures for Institutional Ethics Committee. Available at http://ferci.org/wp-content/uploads/2014/07/1.-Preparation-of-Standard-Operating-Procedures-for-Institutional-Ethics-Committee.pdf
7. NIRRH Ethics Committee for Clinical Studies, 3.5 Vulnerable Population, SOP Code: SOP/ 10/V1.0; Effective date: 20/03/2013. Available at http://www.nirrh.res.in/SOP/10_VulnerablePopulation.pdf
8. Brassil D, Kost RG. Protocol Deviations and Protocol Violations Made Simple. Available at http://heilbrunnfamily.rucares.org/assets/file/Protocol%20Deviations%20and%20Protocol%20Violations%20Made%20Simple%20DBRK%208%201%202013%20FINAL%20(2).pdf
9. International Ethical Guidelines for Health-related Research Involving Humans. Council or International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO). Available at http://cioms.ch/ethical-guidelines-2016/WEB-CIOMS-EthicalGuidelines.pdf

[As accessed on 21st May 2017]

LIST OF ANNEXURES

Annexure No.	Content
I	IEC Member's List
II	Confidentiality and COI agreement for members
II.1	Declaration of conflict of interest for IEC members or investigators
III	Roles and responsibilities of each member of IEC
IV	Application format for investigator initiated full committee or exempt review project
IV.1	Protocol format for investigator initiated full committee or exempt review project
IV.2	Participant information sheet [English]
IV.3	Participant information sheet [Gujarati]
IV.4	Informed consent form [English]
IV.5	Informed consent form [Gujarati]
V	Application format for industry or government initiated full committee review project
VI	Application format for investigator initiated case reports review
VI.1	Protocol format for investigator initiated case reports review
VI.2	Case report consent or assent form [English]
VI.3	Case report consent or assent form [Gujarati]
VII	Checklist for investigators
VIII	Format of response to query letter by investigator
IX	Format of approval letter by Institutional Ethics Committee
X	Site monitoring report [Regulated trial]
X.1	Site monitoring report [Non regulated project]

XI	SAE Report Checklist
XII	WHO tool for causality assessment
XIII	Naranjo ADR Probability Scale
XIV	Format of IEC report to CDSCO in case of SAE
XV	Compensation formula, SAE, Death
XVI	Compensation formula, SAE, Injury other than death