SVT INSTITUTIONAL ETHICS COMMITTEE ON HUMAN RESEARCH GUIDELINES, PROCEDURES & COMPOSITION

OPERATIONAL DEFINITIONS

Multicentre Research: Research that is conducted in more than one place/ centre usually following a common protocol and with multiple investigators. Each centre can further have multiple sites from which participants can be recruited. In certain studies, PIs from centres may be involved in different roles such as coordination, quality control and data management etc for the same common protocol.

Study proposal/ Master Protocol: The common protocol with uniform core objectives, methods, and measurement tools approved by the Advisory Committee. The Master protocol may remain consistent across the sites in multicentre research however the consent form can be modified/ translated as per local requirements.

Scientific Committee (SC): May also be referred to as Central Scientific Advisory Committee (C-SAC)/ National Task Force (NTF) / Technical (Scientific) Advisory Committee (SAC)/ Steering Committee (SC)/ Project Review Committee (PRC). This committee includes a group of independent subject experts apart from investigators involved in the study/ or members of funding agencies/sponsors or its representatives. This committee could be an existing committee or appointed specifically for the study. Undertakes detailed scientific review and its approval. For multicentre studies, it may suggest (if required) waiver for review by other site specific scientific committees in view of time constraints or to avoid duplication.

Monitoring Committee (optional): This committee may be suggested or appointed by the joint ethics committee or sponsors to undertake closer oversight or monitoring. This committee may include experts from funding agencies/sponsors/partners/ EC members or other independent experts or members from EC as per requirement.

Coordinating Principal Investigator (C-PI): Coordinating PI is one who takes the overall responsibility of conducting multicentre research in collaboration with PIs from all the participating centres and is also responsible for ongoing communication between ethics committees and PIs at other participating centres.

Site Principal Investigator (S-PI): The S-PI is the person who takes the responsibility of conducting research at her/his participating centre in the multicentre research. Each centre can have additional co-investigator(s), who may conduct the study within the centre in association with and/or in the absence of the Site PI.

Central Ethics Committee on Human Research (CECHR): A committee appointed by the DG ICMR to act at the national level to guide ICMR regarding complex ethical issues or review research led by ICMR Headquarters Office or referred to it by ICMR institutions, other government Ministries and Departments.

Designated Ethics Committee (DEC): The Ethics Committee usually from the Coordinating Site (or any of the Participating sites), which assumes the responsibility of undertaking a common initial and continuing review of the multicentre research proposal with mutual agreement of all the participating centres. Responsible for conducting an in-depth Joint review and providing suggestions/ recommendations to PEC.

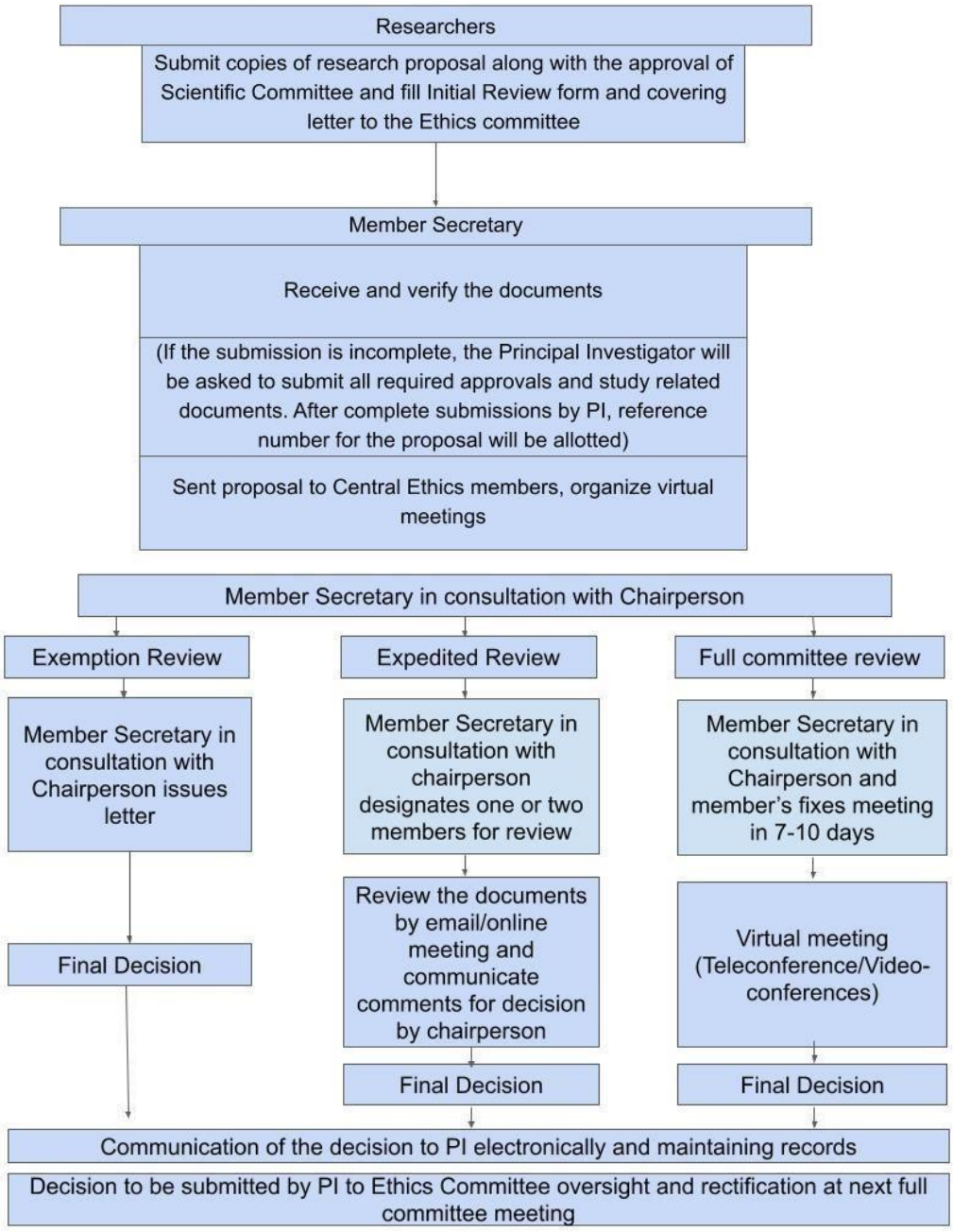
Participating Centre Ethics Committee (PEC): The Participating Centre ECs are located at the various participating centres in multicenter research (including DEC). PECs are responsible for a review of research according to the local requirements and for providing decisions to the participating local sites. They may undertake an expedited review and accept the recommendations (if acceptable) of DEC or decide as per local requirements. They are responsible for monitoring research at the local level.

Joint Ethics Committee Review Meeting: is a meeting coordinated by Designated Ethics Committee (DEC) where the Participating Ethics Committees (PECs) meet for joint discussion amongst the ethics committees of all participating sites in order to undertake a detailed ethics review and to give recommendations followed by final decision making by individual site ECs (PECs).

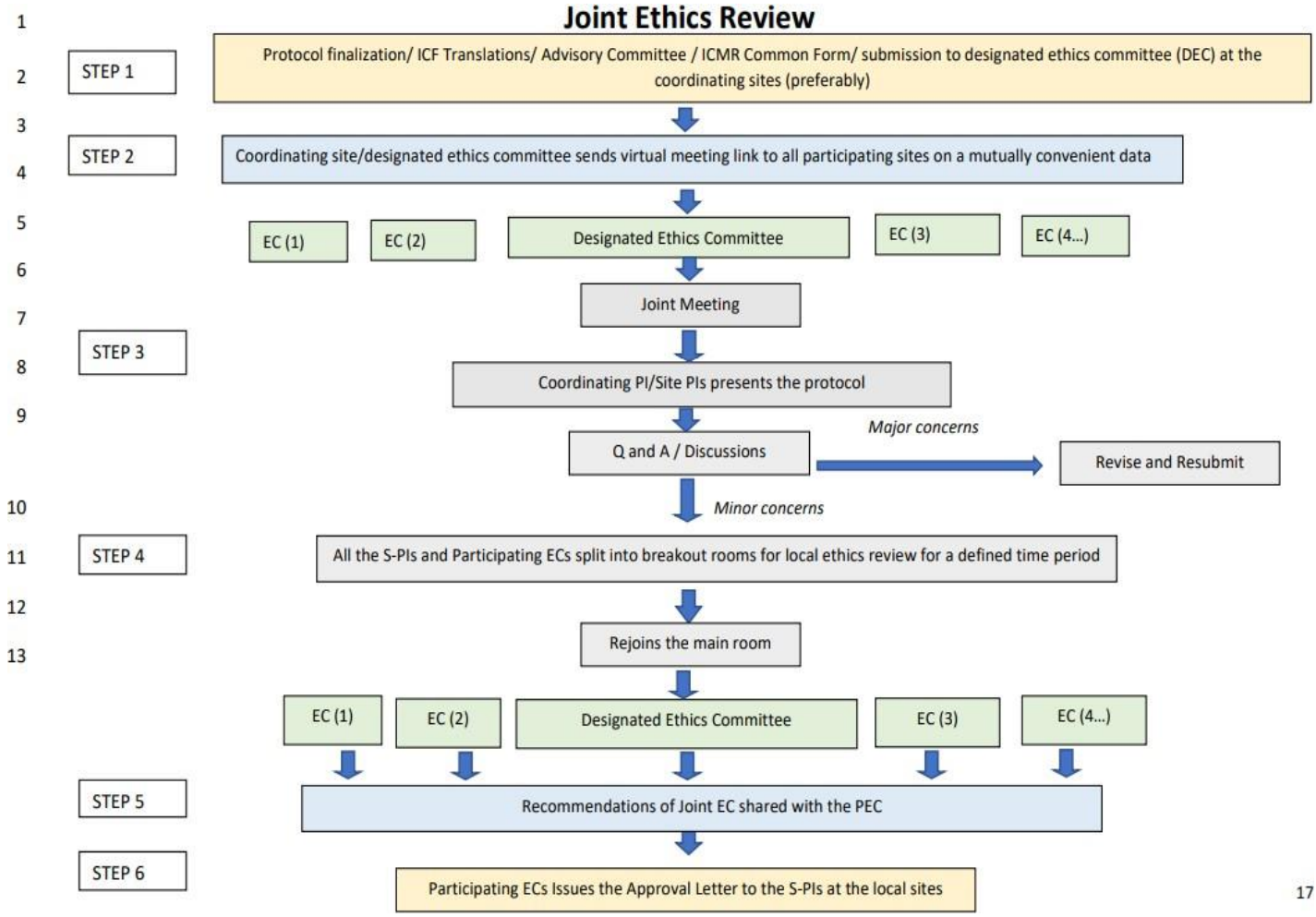
REGISTRATION AND ACCREDITATION OF ECs

1. ECs must ensure that processes are in place to safeguard the quality of ethical review as well as compliance with national/international and applicable regulations.
2. ECs should register with the relevant authority as per the regulatory requirements.
3. Efforts should be made to seek recognition/certification/accreditation from recognized national/international bodies such as Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Association for the Accreditation of Human Research Protection Programmes (AAHRPP), CDSCO and Quality Council of India through National Accreditation Board for Hospitals and Healthcare Providers (NABH) or any other. Such certification/accreditation should be kept updated on a continuing basis.
4. Certification/accreditation are voluntary exercises and help in quality assurance and quality improvement to ensure that ECs follow best practices in protecting the dignity, rights, safety, and well-being of their participants.

COMPOSITION OF ETHICS COMMITTEE REVIEW AND RESPONSIBILITIES - SVT INSTITUTIONAL ETHICS COMMITTEE ON HUMAN RESEARCH



FLOWCHART OF INSTITUITIONAL ETHICS REVIEW



COMPOSITION OF AN ETHICS COMMITTEE

1. ECs should be multi-disciplinary and multi-sectoral.
2. There should be adequate representation of age and gender.
3. Preferably 50% of the members should be non-affiliated or from outside the institution.
4. The number of members in an EC should preferably be between 7 and 15 and a minimum of five members should be present to meet the quorum requirements.
5. The EC should have a balance between medical and non-medical members/technical and non-technical members, depending upon the needs of the institution.

Table- Composition, affiliations, qualifications, member specific roles and responsibilities of an EC

S. No.	Members of EC	Definition/description
1	**Chairperson/** **Vice Chairperson** (optional) Non-affiliated Qualifications - A well-respected person from any background with prior experience of having served/ serving in an EC	•Conduct EC meetings and be accountable for independent and efficient functioning of the committee •Ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations •Ratify minutes of the previous meetings •In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting. •Seek COI declaration from members and ensure quorum and fair decision making. •Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data,

		etc.
2	**Member Secretary/ Alternate Member Secretary** (optional) Affiliated Qualifications - •Should be a staff member of the institution •Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills •Should be able to devote adequate time to this activity which should be protected by the institution	• Organise an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review •Schedule EC meetings, prepare the agenda and minutes •Organise EC documentation, communication and archiving •Ensure training of EC secretariat and EC members •Ensure SOPs are updated as and when required •Ensure adherence of EC functioning to the SOPs •Prepare for and respond to audits and inspections •Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. •Assess the need for expedited review/ exemption from review or full review •Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. •Ensure quorum during the meeting and record discussions and decisions.
3	**Basic Medical Scientist(s)** Affiliated/ non-affiliated Qualifications - •Non-medical or medical person with qualifications in basic medical sciences • In case of EC reviewing	•Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report •For clinical trials, pharmacologists review the drug safety and pharmacodynamics.

	clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist	
4	**Clinician(s)** Affiliated/ non-affiliated Qualifications - •Should be individual/s with recognized medical qualification, expertise and training	• Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics •Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) •Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation. •Thorough review of protocol, investigator's brochure (if applicable) and all other protocol details and submitted documents.
5	**Legal expert/s** Affiliated/ non-affiliated Qualifications - •Should have a basic degree in Law from a recognized university, with experience •Desirable: Training in medical law.	•Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc. •Interpret and inform EC members about new regulations if any
6	**Social scientist/ philosopher/ ethicist/theologian** Affiliated/ non-affiliated	•Ethical review of the proposal, ICD along with the translations. •Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any

	Qualifications - •Should be an individual with social/ behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities	•Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.
7	**Lay person(s)** Non-affiliated Qualifications - •Literate person from the public or community •Has not pursued a medical science/ health related career in the last 5 years •May be a representative of the community from which the participants are to be drawn •Is aware of the local language, cultural and moral values of the community •Desirable: involved in social and community welfare activities	•Ethical review of the proposal, ICD along with translation(s). •Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. •Serve as a patient/participant/ community representative and bring in ethical and societal concerns. •Assess on societal aspects if any

REQUIREMENTS TO BECOME AN EC MEMBER

1. A recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines, if applicable;
2. Either be trained in human research protection and/or GCP at the time of induction into the EC, or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy);
3. Be willing to undergo training or update their skills/knowledge during their tenure as an EC member;
4. Be aware of relevant guidelines and regulations;
5. Read, understand, accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time;
6. Sign a confidentiality and conflict of interest agreement/s;
7. Be willing to place her/his full name, profession and affiliation to the EC in the public domain; and
8. Be committed and understanding to the need for research and for imparting protection to research participants in research.

CRITERIA FOR SELECTION OF MEMBERS OF AN EC

1. Members should be selected in their personal capacities based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the EC.
2. Members are appointed to the EC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting. The role of Chairperson/ Member Secretary is an additional activity to their primary responsibility based on their qualifications. Hence, if the Chairperson is a lawyer, she or he can serve as both the lawyer and the Chairperson.
3. These criteria should be specified in SOPs.

CONTINUAL TRAINING OF EC MEMBERS

1. Members should be trained in human research protection, EC functions and SOPs, and should be conversant with ethical guidelines, GCP guidelines (if applicable) and relevant regulations of the country.
2. EC members should undergo initial and continuing training in human research protection, applicable EC SOPs and related regulatory requirements. All training should be documented.
3. Any change in the relevant guidelines or regulatory requirements should be brought to the attention of all EC members.
4. EC members should be aware of local, social and cultural norms and emerging ethical issues.

ROLES AND RESPONSIBILITIES OF EC

1. The basic responsibility of an EC is to ensure protection of the dignity, rights, safety and well-being of the research participants.
2. The EC must ensure ethical conduct of research by the investigator team.
3. The EC is responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.
4. The EC should perform its function through competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations.
5. The EC must ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.
6. The EC should assist in the development and education of the research community in the given institute (including researchers, clinicians, students and others), responsive to local healthcare requirements.
7. Responsibilities of members should be clearly defined. The SOPs should be given to EC members at the time of their appointment.
8. The Secretariat should support the Member Secretary and Alternate Member Secretary (if applicable) in all their functions and should be trained in documentation and filing procedures under confidentiality agreement.
9. The EC should ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.
10. The EC reviews progress reports, final reports and Adverse Event/Serious Adverse Events and gives needful suggestions regarding care of the participants and risk minimization procedures, if applicable.
11. The EC should recommend appropriate compensation for research related injury, wherever required.
12. The EC should carry out monitoring visits at study sites as and when needed.
13. The EC should participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.
14. The EC may see that conduct of same/similar research by different investigators from the same institution is harmonised. ‘Me too’ research (replicative) should not be encouraged and submission of the same research to different funding agencies should not be accepted.

DOCUMENTS TO BE MAINTAINED BY EC FOR RECORD

Type of document Document specifics	**Type of document Document specifics**
Administrative documents	● Constitution and composition of the EC ● Appointment letters ● Signed and dated copies of the most recent curriculum vitae of all EC members ● Signed confidentiality agreements ● COI declarations of members ● Training records of EC members ● Financial records of EC ● Registration/accreditation documents, as required ● A copy of national and international guidelines and applicable regulations Regulatory notifications ● Meeting-related documents ● Agenda and minutes ● All communications received or made by the EC SOPs
Proposal-related document	● One hard copy and a soft copy of the initial research proposal and all related documents ● Decision letters ● Any amendments submitted for review and approval ● Regulatory approvals ● SAE, AE reports ● Protocol deviations/violations ● Progress reports, continuing review activities, site monitoring reports AND All correspondence between the EC and researchers ● Record of notification issued for premature termination of a

	study with a summary of the reasons ● Final report of the study ● Publications, if any

RECORD KEEPING AND ARCHIVING

1. All documentation and communication of an EC should be dated, filed and preserved according to written procedures.
2. Confidentiality should be maintained during access and retrieval procedures by designated persons.
3. All active and inactive (closed) files should be appropriately labelled and archived separately in designated areas.
4. Records can be maintained in hard copies as well as soft copies.
5. All records must be archived for a period of at least 3 years after the completion/ termination of the study.
6. Documents related to regulatory clinical trials must be archived for 5 years after the completion/termination of the study or as per regulations.
7. Records may be archived for a longer period, if required by the sponsors/regulatory bodies.
8. EC records should be accessible for inspection by authorised representatives of regulatory agencies.

GUIDELINES FOR SUBMISSION OF RESEARCH PROPOSAL FOR EC APPROVAL

Applicants for evaluation of research projects: EC will consider the applications from the following:

1. Principal Investigators
2. Sponsors
3. Clinical Research Organisation (CRO)

Researchers should submit research proposals as soft or hard copies to the Secretariat for review in the prescribed format and required documents as per EC SOPs.

1. A recognized institution/centre wanting to conduct any prospective, retrospective studies (on drugs, investigational techniques, behavioural or dietary interventions, surgical techniques or use of biomedical devices) involving human subjects or patients can submit the proposed research protocol (RP) along with the case record form (CRF) drawn as per the GCP / ICMR guidelines.

2. The protocol should be typed in English. It should have the names, designations and dated signatures of the principal investigator (PI) and Co- investigators (CI). It should be submitted through the head of the institution or appropriate authority. If the study involves collaboration with another department or outside centre, the collaborators' signatures should also be included. The proforma should include details of the clinical phase of drug trial, type of patients, place of study, duration of study, investigations to be carried out, the names of the sponsoring agencies, the cost of the trial to the sponsors and the cost to each of the participating centres in terms of manpower, man hours and actual costs, the permissions from Drugs Controller General of India (DCGI), ICMR or any other appropriate authorities,import permissions if the drug is imported and the existing facilities and infrastructure of the institutes / centres conducting the studies.

3. All studies on drugs not marketed in India or a new combination or ingredients marketed separately, or plan to use any drug (from India or from outside) require permission from DCGI. A copy of the permissions should be submitted. If the DCGI permission is not available, the copy of the application to the DCGI can be submitted to EC which may give a provisional approval subject to DCGI PERMISSION. The study cannot begin until a copy of the DCGI approval is received by BEC.

For drugs investigated or marketed internationally the investigational status and marketing status in all different countries should be mentioned. For multicentric studies the names of all centres and investigators should be

made available to the Ethics Committee and appropriate permissions from DCGI (when required), ICMR, Health Ministry and HMSC should be submitted to EC. For Ayurvedic, Homoeopathic, Unani or herbal drugs, a copy of the manufacturing license issued by FDA, to the company or institute concerned, will facilitate clearance from the Committee. Alternatively data of the ingredients as mentioned in the Standard Reference Text of the Alternative Systems of Medicine will be required. In addition, the product under investigation should have identifiable biological markers (Passport data) as well as SOP for its manufacture, to ensure Standardization.

For Ayurvedic, Homoeopathic, Unani or herbal drugs, a copy of the manufacturing licence issued by FDA, to the company or institute concerned, will facilitate clearance from the Committee. Good Ayurvedic Research Practices (GARP):Testing of Ayurvedic products will be consistent with Modern Standard of Ethics in Medicine,as per the practices mentioned in Good Ayurvedic Research Practices in a study involving Traditional Systems of Medicine , an investigator, who is a specialist in that system, has to be included as a co-investigator. (Later- Similarly, an expert member from that system should be present in all the proceedings of the EC related to that study.

DOCUMENTS REQUIRED FOR SUBMISSION:

EC will require the following documents to be submitted by the applicant for evaluation of projects: (All documents including the covering letter should be in the form of word file or PDF attachments)

i) Prescribed form of EC- Appendix No---

ii) Cover letter indicating the title of the study, number of subjects, and names of centres (sites) to be involved-details provided later.

iii) Investigator's brochure with data on preclinical and clinical studies carried out till date and complete safety data

iv) Study protocol and amendments if any

v) Case Record Form

vi) Patient information sheet along with the translations in regional languages

vii) Copy of the Informed Consent Form along with the translations in regional languages

viii) Subject recruitment procedures and advertisements if any

ix) Details of study sites

x) Copies of permission from DCGI or any appropriate regulatory authorities/ or copy of application to regulatory authority.

xi) Study monitoring procedures if any including Data Safety Monitoring Board (DSMB) if applicable

xi) Monitoring procedures if any

xii) Copy of permission from any other Ethics Committee for the same study at another centre, copy of Health Ministry Screening Committee (HMSC) for International Collaboration

xiii) CTRI registration number

xiv) Copy of registration certificate or Quality Control certificate of the laboratories which will participate in laboratory procedures

xv) Biodata and copy of recent GCP certificate of the Principal Investigatorand Co-Investigator

xvi) Package insert and label of the IP

xvii) Publication Policy

All protocols/projects dealing with human subjects are to be preceded by the following checklist irrespective of whether they are for undergraduate or postgraduate study, interventional or non-interventional study or behavioural study, and the Principal Investigator is answerable for any lapses in clinical applications.

Checklist for protocol submission:

Sr. No.	Item	Yes	No	Not Applicable
1	Cover letter signed by the PI /Sponsor as an attachment giving the title and general information and a complete numbered list of all documents submitted as listed below and any additional documents when required			
2	Application form			
2	First Page- with Title, Address, Names & Signatures of Investigators, Co-Investigators, Centres, Sponsors			
3	Title- must include type of study, population for study, intervention or observational subject, site of study			
4	Type of Clinical study, address of centres, population to be studied, duration of study			
5	Expected cost of study			
6	Permissions from authorities like departmental or institutional head, DCGI, State authorities, marketing license, Import license when applicable, CTRI registration, HMSC permission for international collaboration			
7	Copy of EC permission from another centre if available			
8	List of project staff & Responsibilities			
9	Infrastructure facilities available, to be acquired			
10	Interventional drugs- Manufacturing batch no, stock received, preservation, shelf life			

11	Instrumental intervention- Manufacturing Licence, Model No, Year of manufacture etc			
12	Nutritional products-preparation, preservation, shelf life			
13	Sample size, study & control subjects when applicable, statistical basis			
14	Period of enrollment, Total duration of study, period for Statistical analysis- Duration of follow up when required			
15	Ayurvedic, Homeopathic, Unani or herbal drugs- manufacturing license, Passport data of plants & extracts, Certificate of analysis, details of types of extracts, formulation			
16	Preclinical data when applicable			
17	Review of Literature and rationale- old as well as recent, summary tables with authors and years of publications			
18	Purpose of the study			
19	Primary Objectives			
20	Secondary Objectives			
21	Investigator’s brochure- summary of preclinical and previous clinical trial data			
22	Study Protocol with Amendments if any			
23	Case Record Form, Questionnaire, Food Frequency form, Activity form , QoL Assessment forms			
24	Subject information sheet with translations			
25	Informed Consent form with statement on confidentiality,			

	Insurance when applicable, translations, Assent forms for children aged 7 years or more, Waiver of consent			
26	Information about EC and Contact information on Consent form			
27	Subject recruitment procedures, advertisements			
28	Study site details, co-investigators			
29	Subject Inclusion /Exclusion criteria			
30	Treatment or Intervention details, package insert, copy of the label			
31	Assessment criteria			
32	Investigations, amount of blood to be collected at each visit and total amount collected during the study, laboratory details, QC certificates, references for methods used			
33	Monitoring Procedures including DSMB when required			
34	Criteria for discontinuation of subject or for the study, Fail Safe procedures, Details of Clinician on project for Student's project when needed, procedures for subjects excluded from study but requiring referral Eg Severe anaemia, complications			
35	Adverse Event and Adverse Drug Reaction Reporting forms and procedures and plan of management, Data safety, confidentiality procedures			
36	Subject Insurance details when applicable - copy of insurance policy, subject compensation details when applicable			
37	Biodata of PI, Co-I, Copy of Recent GCP certificate of PI, Co-I			

38	Signed undertaking by PI			
39	Publication policy			

- Appropriate fees for the evaluation will be charged depending on the type of Institute/Company submitting the project and the nature of the project.
- Applicants will be informed regarding the amount to be paid, and date for the review on receipt of the proposal. A demand draft in favour of "[Name of EC]" should be forwarded before the meeting is scheduled.
- Projects on Alternative and Indian System of medicine must include an expert in the system as a co-investigator with the biodata. All collaborations must be mentioned.

SUBMISSION AND REVIEW PROCEDURES

TYPES OF REVIEW

SR. No.	Type of Review	
1	Exemption from review	Proposals with less than minimal risk where there are no linked identifiers, for example; •Research conducted on data available in the public domain for systematic reviews or meta-analysis; •Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person; •Quality control and quality assurance audits in the institution; •Comparison of instructional techniques, curricula, or classroom management methods; •Consumer acceptance studies related to taste and food quality; and •Public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).
2	Expedited review	Proposals that pose no more than minimal risk may undergo expedited review, for example; •Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples; •Research involving clinical documentation materials that are non-identifiable (data, documents, records); •Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s); •Revised proposals previously approved through expedited review, full review or continuing review of approved proposals;

		•Minor deviations from originally approved research causing no risk or minimal risk; •Progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and •For multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review. •Research during emergencies and disasters (See Section 12 for further details).
3	Full committee review	All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, some examples are; •Research involving vulnerable populations, even if the risk is minimal; •Research with minor increase over minimal risk; •Studies involving deception of participants; •Research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee; •Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk; •Major deviations and violations in the protocol; •Any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment; •Research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need;

		•Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

SPECIFIC GUIDELINES

1. Researchers should submit research proposals as soft or hard copies to the Secretariat for review in the prescribed format and required documents as per EC SOPs. The EC should prepare a checklist for the required documents. This list is subject to modifications, depending on the type of research, EC SOPs and institutional policies.
2. The Member Secretary/Secretariat shall screen the proposals for their completeness and, depending on the risk involved, categorise them into three types, namely, exemption from review, expedited review, and full committee review.
3. A researcher cannot decide that her/his proposal falls in the exempted, expedited or full review category. All research proposals must be submitted to the EC. The decision on the type of review required rests with the EC and will be decided on a case-to-case basis. Researchers can approach the EC with appropriate justification for the proposal to be considered as exempt, expedited or if waiver of consent is requested.
4. Expedited review can be conducted by Chairperson, Member Secretary and one or two designated members or as specified in SOPs.
5. Approval granted through expedited review and the decisions of the SAE subcommittee must be ratified at the next full committee meeting.
6. EC members should be given enough time (at least 1 week) to review the proposal and related documents, except in the case of expedited review.
7. All EC members should review all proposals. However, the EC may adopt different procedures for review of proposals in accordance with their SOPs.
8. The EC may adopt a system for pre-meeting peer review by subject experts and obtain clarifications from the researchers prior to the meeting in order to save time and make the review more efficient during the full committee meeting, especially in institutions where there are no separate scientific review committees.
9. The EC may have a system of appointing primary and secondary reviewers. The Member Secretary should identify the primary and secondary reviewers for reviewing the scientific content and the ethical aspects in the proposal as well as the informed consent document, depending upon their individual expertise. These

experts may be invited to the EC meeting or join via video/teleconference but will not participate in final decision making.

10. The EC should meet regularly, adopt best practices, try to reduce turnaround time or have procedures in place for early decision making so that research is not delayed.

SOP OF PROTOCOL REVIEW BY EC

Checklist for scientific and ethical approval:

1. The research protocol must have anticipated social value. The outcome of the research should be relevant to the health problems of society.
2. Valid scientific methods and conduct of the study: as poor science can expose research participants or communities to risks without any possibility of benefit.

a. Determine that the research methods are scientifically sound, and examine the ethical implications of the chosen research design or strategy.

b. Raise scientific concerns (even if the study has prior approval of a scientific committee) if it may affect quality of research and or safety of research participants.

3. Benefit-Risk Assessment: The benefits accruing from the planned research either to the participants or to the community or society in general must justify the risks inherent in the research. Risks may be physical, psychological, economic, social or legal and harm may occur either at an individual level or at the family, community or societal level.

a. First look at the intervention under investigation and assess its potential harm and benefits and then consider the aggregate of harm and benefits of the study as a whole.

b. Review plans for risk management, including withdrawal criteria with rescue medication or procedures.

c. Give advice regarding minimization of risk/discomfort wherever applicable.

4. Qualifications of researchers and adequacy assessment of study sites: Review the suitability of qualifications and experience of the PI to conduct the proposed research along with adequacy of site facilities for participants.

5. Monitoring and auditing the conduct of the research: constitution of a Data and Safety Monitoring Board (DSMB) if applicable (for example in clinical trials).

6. Selection of the study population and recruitment of research participants:

a. Recruitment should be voluntary and non-coercive.

b. Participants should be fairly selected as per inclusion and exclusion criteria.

c. Selection of participants should be distributive such that a particular population or tribe or economic group is not coerced to participate or benefit.

d. Participants should be able to opt out at any time without their routine care being affected.

e. No individual or group of persons must bear the burden of participation in research without accruing any direct or indirect benefits.

f. Vulnerable groups may be recruited after proper justification is provided.

7. Payment for participation:

a. Review Plans for payment for participation, reimbursement of incurred costs, such as travel or lost wages, incidental expenses and other inconveniences.

b. Determine that payments are not so large as to encourage prospective participants to participate in the research without due consideration of the risks or against their better judgement. No undue inducement must be offered.

8. Protection of research participants' privacy and confidentiality: Examine the processes that are put in place to safeguard participants' privacy and confidentiality.

9. Community considerations:

a. Proposed research should not lead to any stigma or discrimination or harm.

b. Carefully review the plans for communication of results to the community at the end of the study (how the benefits of the research will be disseminated to the community)

10. Disclosure or declaration of potential COI: Review any declaration of COI by a researcher and suggest ways to manage these. Manage COI within the EC and members with COI should leave the room at the time of decision making in a particular study.

11. Plans for medical management and compensation for study related injury:

a. Review the proposed plan for tackling any medical injuries or emergencies

b. Ascertain the source and means for compensation for study related injury

12. The informed consent process: Review

a. the process used for obtaining informed consent, including the identification of those responsible for obtaining consent and the procedures adopted for vulnerable populations;

b. the adequacy, completeness and understandability of the information to be given to the research participants, and when appropriate, their LARs;

c. contents of the patient/participation information sheet including the local language translations; or back translations of the informed consent document in English, wherever required;

d. provision for audio-visual recording of consent process, if applicable, as per relevant regulations; and

e. If consent waiver or verbal/oral consent request has been asked for, this should be reviewed by assessing whether the protocol meets the criteria.

TYPES OF DECISIONS AFTER REVIEW BY EC

An EC can give one of the following decisions:

1. approved – with or without suggestions or comments;
2. Revision with minor modifications/amendments – approval is given after examination by the Member Secretary or expedited review, as the case may be;
3. Revision with major modifications for resubmission – this will be placed before the full committee for reconsideration for approval; or
4. Not approved (or termination/revoking of permission if applicable) – clearly defined reasons must be given for not approving/terminating/revoking of permission.