SRI JAYENDRA SARASWATHI AYURVEDA COLLEGE & HOSPITAL
Dept. of Ayurveda of Sri Chandrasekharendra Saraswathi Viswamahavidyalaya
Deemed to be University u/s 3 of UGC act 1956,
Accredited with "A" Grade by NAAC
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INSTITUTIONAL ETHICS COMMITTEE-GUIDELINES

1) DUTIES OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

The institutional Ethics Committee has to ensure a proper review of all ethical aspects of the project proposals in an objective manner,

- to ensure the scientific soundness of the research proposal by a scientific review committee,
- to provide advice to researchers on all aspects of welfare and safety of research participants,
- to protect the dignity, rights and well being of potential research participants
- to ensure that the universal ethical values and international scientific standards are expressed in terms of local community values and customs, and
- to assist in the developments and education of a research community responsive to local health care needs.

2) ROLES AND RESPONSIBILITIES OF IEC MEMBERS

- Regularly attend and actively participate in the EC meetings
- Review, discuss and consider research proposals submitted for evaluation.

Reviewers

- For each proposal will review the study. Later, if any other issues the other IEC members can voice their comments/suggestions.
- Discuss serious adverse event reports and recommend appropriate action(s)
- Review the progress reports and monitor ongoing studies as appropriate.
- Evaluate final reports and outcomes
- Maintain confidentiality of the documents and deliberations of IEC meetings.

Declare

- Any conflict of interest
- Research if deemed necessary, should suggest any changes that may be necessary to be included
- Conduct monitoring visits for any research proposal, if needed.

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3) COMPOSITION OF ETHICS COMMITTEE

- Chairperson: should be from outside the Institution.
- Number of members can be between 8 and 12. Minimum of 5 members must be present to constitute Quorum for the meeting.
- Independence and competence is the hallmark of this multisectorial and multi disciplinary committee.
- One to two persons from Basic medical sciences • One to two clinicians from various institutes • One legal expert or retired Judge • One social scientist/representative • One lay person • One pharmacologist • Member – Secretary • Invited members depending on the need for a particular meeting

4) TERMS OF REFERENCE AND REVIEW PROCEDURES

- The IEC should be aware of their role and responsibilities as Committee Members.
- Each Committee should have its own operating procedures available with each member
- Any change in the regulatory requirement should be brought to the notice of members, keeping in view the National and International developments.
- The ethical review should be done through formal meetings and discussion should not be taken through circulation of proposals.
- Every research proposal on human subjects should be reviewed scientifically, evaluated in terms of risks and benefits with proper justification
- Scientific evaluation should be done completely prior to ethical review
- The Committee should evaluate for the adequacy of documentation to ensure privacy confidentiality and legal aspects.
- All proposals on biomedical researches involving human subjects should be cleared by an appropriately constituted Institutional Ethics Committee (IEC), to safeguard the welfare of the rights of the subject involved.
- The investigator should seek the opinion of Institutional Ethics Committee regarding suitability of the protocol, methods and documents to be used ,obtaining their informed consent including adequacy of the information being provided to the subjects.
- The Ethics Committees are entrusted not only with the initial view of the proposed research protocols prior to the initiation of the projects but also have a continuing responsibility of regular monitoring for the compliance of the ethics of the approved programme till the same are completed.

- Interim review: can be resorted to instead of waiting for the scheduled time of the meeting and decisions can be taken urgently and should be brought to the notice of the main committee
- All research involving human subjects should be conducted in accordance with three basic ethical principles, namely respect for person, beneficence and justice.

(A) RESPECT FOR PERSONS includes at least two fundamental ethical considerations, namely 1. Respect for autonomy It includes the idea that an individual is free to choose and to act. Both rational capacity and freedom from constraint are necessary elements. "Respect for persons" includes respecting the decisions of autonomous beings. 2. Protection for those with impaired or diminished autonomy It means a recognition by the commission that these people are not capable of self determination at all times and in all circumstances.

(B) BENEFICENCE – includes the ethical obligation to maximize benefits and minimize harms and wrongs.

(C) JUSTICE – In the ethics of research involving human subjects the principle primarily refers to distributive justice, which means equitable distribution of both burden and the benefits of participation in research.

- The study should add to the existing knowledge or should help in innovation for the new knowledge and should benefit the society and humanity by enlarge.
- Scientifically sound: The research should be scientifically valid sound study design, appropriate statistical analysis, the feasibility of the study, and precise scientific objective.
- Fair selection of the study samples: Selection of the vulnerable group for research with risky outcomes is a major ethical problem. Appropriate selection of the sample based on the merit of the study and justice to the sample is of most importance.
- Favorable risk–benefit ratio: Maximum benefit and minimum risk care should be taken to have minimal risk to the patient in comparison to the benefit. The benefit is assessed on the total good from the research to the individual and the society. Patients should not be exploited.
- There should also be review of research design of the trial and risk to the population recruited in the trial.

Informed consent: It should be taken from every sample recruited in the study; it should be voluntary, legal, and comprehending and should be recorded and maintained as per regulations of the country.

Autonomy of the participants involved in research is very crucial; the participants need to be informed of the risk and benefit involved in the trial, and they have the right to withdraw from the study at any given time.

- The statement should clearly explain the study participants about the purpose of research, duration, the procedure/intervention involved, the possible risk involved, benefit to the participant, referrals in case of emergency, and compensation to the study participants.
- The investigator should maintain confidentiality regarding the participants involved in the trial. The consent has to be explained in the language the patient understands the best, in simple and not technical words. The consent has to be understood, voluntary, and the participant has the right to withdraw from the study anytime
- Ethics committee shall review the research protocol to safeguard the right, well- being, and safety of the trial participants.
- In the case of any adverse event during the clinical trial, the ethics committee shall analyze
- The committee shall maintain all th information regarding the clinical trial for at least 5 years after the completion of the trial.
- For clearing the protocol for a clinical trial, the ethics committee should have the quorum of at least five members: Basic scientist, legal expert, clinician, social scientist, and layperson.
- The principal investigator and the Ethical Committee members are expected to have adequate knowledge on Good Clinical Practice guidelines for clinical trials. Members representing ethics committee should have a postgraduate degree, possess sufficient scientific knowledge, and should be aware of their roles and responsibilities as board members.