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INSTITUTIONAL ETHICAL COMMITTEE (IEC) FOR CONDUCT OF TRIALS INVOLVING HUMAN PARTICIPANTS

Institutional Ethical Committee (IEC) is constituted in the University as per the protocol for conducting research work & clinical trials. This committee is also mandatory to initiate any research projects related to clinical trials with patient participation in attached hospital of the University (MSM Institute of Ayurveda) as per directions of GCP (Good Clinical Practices) issued by Ministry of AYUSH, GoI.

Ethics Committee:

The sponsor and / or investigator should seek the opinion of an institutional EthicsCommittee regarding suitability of the Protocol, methods and documents to be used in recruitment of Subjects and 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 initiation of the projects but also have a continuing responsibility of regular monitoring for the compliance of the Ethics of the approved programmes till the same are completed. Such an ongoing review is in accordance with the "Ethical guidelines for Biomedical Research on Human participants" 2006, as amended from time to time.

Basic Responsibilities The basic responsibility of an IEC is to ensure a competent review of all ethical aspects of the project proposals received and execute the same free from any bias and influence that could affect their objectivity. The IECs should specify in writing the authority under which the committee is established, membership requirements, the terms of reference, the conditions of appointment, the offices and the quorum requirements.

Composition of IEC

a. IEC should be multidisciplinary and multi-sectorial in composition. Independence and competence are the two hallmarks of an IEC.

b. The number of persons in an Ethics Committee to be kept fairly small (5-7 members). It is generally accepted that a minimum of five persons is required to compose a quorum. There is no specific recommendation for a widely acceptable maximum number of persons but it should be kept in mind that too large a committee will make it difficult in reaching consensus opinion. 12 to 15 is the maximum recommended number

c. The Chairperson of the committee should preferably be from outside the Institution and not head of the same Institution to maintain the independence of the committee. The Member

Secretary who generally belongs to the same Institution should conduct the functioning of the Committee.

Other members should be a combination of medical/non-medical, scientific and non-scientific persons including lay person to reflect the differed viewpoints. The composition may be as follows:-

1. Chairperson- A technical person with research background
2. Member secretary
3. Clinicians -1-2 Ayurvedic practitioners/ clinicians from different Institutes
4. Basic medical scientists- 1-2 basic medical scientists (one pharmacologist and one preferably from Dravyaguna / Rasa shastra / BhaishajyaKalpana).
5. Legal Expert- One Legal expert or retired Judge
6. One Social Scientist / philosopher / ethicist / theologian / representative of NonGovernmental Voluntary Agency
7. One lay person from the community

The Ethics Committee at any Institution can have as its members, individuals from other Institutions or Communities if required. There should be adequate representation of age, gender, community; etc. in the Committee to safeguard the interests and welfare of all sections of the community/Society. Members should be aware of local, social and cultural norms, as this is the most important social control mechanism. If required concerned subject experts could be invited to offer their views.

This committee shall evaluate all the research projects of the University which involve any intervention related involving human participants.

Terms of Reference for IECs

The IEC members should be made aware of their role and responsibilities as committee members. Any change in the regulatory requirements should be brought to their attention and they should be kept abreast of all national and international developments in this regard. The Terms of References should also include a statement on Terms of Appointment with reference to the duration of the term of membership, the policy for removal, replacement and resignation procedure etc. Each committee should have its own operating procedures available with each member.

• The TOR for the IEC and its members should be clearly specified by the institution in the IEC SoPs (Please refer Annex VI for the List o fSoPs/

• Every IEC should have written SoPs according to which the committee should function.

• The IEC can refer to ICMR guidelines in preparing the SoPs for all biomedical and health research and to CDSCO guidelines for drug and device trials under the purview of the licensing authority. The SOPs should be updated periodically to reflect changing requirements. A copy of the latest version of SOPs should be made available to each member and they should be trained on the SOPs. The SOPs must be available in the secretariat of the

IEC as both hard and soft copies. The scope, tenure and renewal policy of the IEC should be stated.

• Members of the IEC should not have any known record of misconduct.

Review Procedures

The Ethics Committee should review every research proposal on human participants within reasonable period of time. It should ensure that a scientific evaluation has been completed before ethical review is taken up. The Committee should evaluate the possible risks to the participants with proper justification, the expected benefits and adequacy of documentation for ensuring privacy, confidentiality and justice issues. The ethical review should be done through formal meetings and should not resort to decisions through circulation of proposals.

Submission of Application

The Investigator should submit an appropriate application to the IEC in a prescribed format along with the study protocol at least three weeks in advance. The application should include the following:

• Clear research objectives and rationale for undertaking the investigation in human participants in the light of existing knowledge.
• Recent curriculum vitae of the Investigators indicating qualification and experience.
• Participant recruitment procedures.
• Inclusion and exclusion criteria for entry of participants in the study.
• Precise description of methodology of the proposed research, including intended dosages and routes of administration of drugs, planned duration of treatment and details of invasive procedures if any.
• A description of plans to withdraw or withhold standard therapies in the course of research.
• The plans for statistical analysis of the study.
• Procedure for seeking and obtaining informed consent with sample of participant information sheet and informed consent forms in English and vernacular languages.
• Safety of proposed intervention and any drug to be tested, including results of relevant laboratory and animal research.
• For research carrying more than minimal risk, an account of plans to provide medical therapy for such risk or injury or toxicity due to over-dosage should be included.
• Proposed compensation and reimbursement of incidental expenses.
• Storage and maintenance of all data collected during the trial.
• Plans for publication of results - positive or negative - while maintaining the privacy and confidentiality of the study participants.
• A statement on probable ethical issues and steps taken to tackle the same.
• All other relevant documents related to the study protocol including regulatory clearances.
• Agreement to comply with national and international GCP protocols for clinical trials.
• Details of Funding agency / Sponsors and fund allocation for the proposed work.

Decision Making Process

The IEC should be able to provide complete and adequate review of the research proposals submitted to them (at least 1 week) to review the proposal and related documents, except in the case of expedited review. It should meet periodically at frequent intervals to review new proposals, evaluate annual progress of ongoing ones and assess final reports of all research activities involving human beings through a previously scheduled agenda, amended wherever appropriate.

The decision must be taken by a broad consensus after the quorum requirements are fulfilled to recommend / reject / suggest modification for a repeat review or advice appropriate steps. The Member Secretary should communicate the decision in writing.

Types of the decision bv the IEC

An IEC can give one of the following decisions:

• approved - with or without suggestions or comments;
• revision with minor modifications/amendments — approval is given after examination by the Member Secretary or expedited review, as the case may be;
• revision with major modifications for resubmission - this will be placed before the full committee for reconsideration for approval; or
• Not approved (or termination/revoking of permission if applicable) - clearly defined reasons must be given for not approving/terminating/revoking of permission.
• A member must voluntarily withdraw from the IEC while making a decision on an application which evokes a conflict of interest which should be indicated in writing to the chairperson prior to the review and should be recorded so in the minutes.
• If one of the members has her/his own proposal for review, then the member should not participate when the project is discussed.
• A negative decision should always be supported by clearly defined reasons.
• An IEC may decide to reverse its positive decision on a study in the event of receiving information that may adversely affect the benefit/risk ratio.
• The discontinuation of a trial should be ordered if the IEC finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.
• In case of premature termination of study, notification should include the reasons for termination along with the summary of results conducted till date.

The following circumstances require the matter to be brought to the attention of IEC:

• Any amendment to the protocol from the originally approved protocol with proper justification;
• Serious and unexpected adverse events and remedial steps taken to tackle them;
• Any new information that may influence the conduct of the study.
• If necessary, the Applicant/Investigator may be invited to present the protocol or offer clarifications in the meeting. Representative of the participant groups or interest groups can be invited during deliberations to offer their viewpoint.
• Subject Experts may be invited to offer their views, but should not take part in the decision making process. However, her/his opinion must be recorded.

• Meetings are to be Minutes which should be approved and signed by the Chairperson.

Interim Review

The IEC should decide and record the special circumstances and the mechanism when an interim review can be resorted-to instead of waiting for the scheduled time of the meeting. This can be done for the following reasons:

i) Re-examination of a proposal already examined by the IEC;
ii) ii) Research study of a minor nature such as examination of case records etc.;
iii) iii) An urgent proposal of national interest.

Record Keeping

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

Special Considerations

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

The conduct and record keeping of IEC shall be done by MSM Institute of Ayurveda.