Mahatma Gandhi Mission's
Medical College & Hospital
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RESPONSIBILITIES OF ETHICS COMMITTEE

1. To ensure independent ,competent and timely review of all ethical aspects of the project proposals in order to safeguard the dignity, rights, safety and well being of all actual and potential research participants.
2. IEC should review of the ethics of proposed studies before the commencement of a study and regularly monitor the ongoing studies
3. Regular Appropriate training of all participants in ICH GCP & NDCT 2019 .
4. To maintain confidentiality of all documents obtained and discussions during the review process .
5. All members should allocate adequate time for reviewing the proposals.
6. All members should put on record various interest financial or otherwise to avoid conflict of interest.
7. All members should give unbiased and non -judgemental decision's about the proposals.

INDIVIDUAL RESPONSIBILITIES OF MEMBERS OF ETHICS COMMITTEE.

RESPONSIBILITIES OF MEMBER SECRETATY

1. Planning of meeting calendar
2. Coordination of meeting by
    - Circulating agenda & documents
    - Reminders
    - Maintaing attendance
    - Maintaining minutes of meeting
3. Ensuring timely submission of documents.
    a) Clinical study proyocol
    b) Investigator brochure and safety information
    c) Informed written consent
    d) DCGI approval or submission letter.
    e) Investigators undertaking.
    f) Certificate of liability insurance.
    g) Current CV of principle investigator.
    h) Other project specific documents.
    i) Draft copy of agreement between Sponsor/CRO/ Institution/SMO/Principle investigator.
    j) Institutional ethics committee fees.
    k) institutional ethics committee submission form.
4. Circulating minutes of meetings.
5. Communication with investigators regarding EC decisions.

6. Acknowledging various documents related to ongoing trials.
    a) Amendments
    b) SAE notifications
    c) safety reports
    d) protocol deviations
    e) annual reports
    f) CTRI letter/ NO.

7. Communicating with DCGI regarding various queries.
8. Record keeping of EC related documents.
    a. The constitution & composition of the EC
    b. Curriculum vitae of all the EC members.
    c. Standard operating procedure of the ethics committee.
    d. National and international guidelines.
    e. Copies of EC submission documents.
    f. All correspondence with EC members, investigators and DCGI.
    (agenda of all meetings, Minutes of all meetings, Copies of decisions communicated to the applicants, Records of all notifications to IEC by PI, Final report of study.)
9. Training details of EC members.

Role of lawyer.

1. Review of CTA
    A. Parties
    B. Details of protocol (No., title, date, version)and PI
    C. Statement of work- Scope of agreement, term, responsibilities of parties.
    D. Payment details--- Payee name address, PAN No., Account No.
2. Confidentiality
3. Indemnification
4. Insurance
5. Dispute resolution & arbitration
6. Termination
7. Budget
8. Record retention & site audits
9. Intellectual property rights
10. Review of ICF
    A. Nature & duration of study stating it as research.
    B. Duration of participants with number of participants.
    C. Procedures/ investigations to be performed.
    D. Foreseeable risks and discomforts.
    E. Benefits to participant, community or medical profession as may be applicable.
    F. Policy of compensation
    G. Availability of medical treatment for such injuries or risk management.

H. Alternative treatments if available.

I. Steps taken for ensuring confidentiality.

J. No loss of benefit on withdrawal .

K. Benefits sharing in the count of commercialization.

L. Contact details of PI/Co PI In multicentric studies for asking more information related to the research or in case of injury.

M. Contact details of chairman of IEC for appeal against violation of more information related to the research or in case of injury.

Role of clinicians --ICF & PROTOCOL

Review of protocol:

1. Clear research objectives & rationale for undertaking the investigation in human participants in the light of existing knowledge.
2. Participant recruitment procedures.
3. Inclusion & exclusion criteria for entry of participants.
4. Statistical methodology, including sample size-potential for reaching conclusion with the smallest number of participants.
5. Appropriateness of type of study design (observational ,experimental, pilot, randomized, blinded etc.) in relation to the objectives of the study.
6. Intended intervention, dosages of drugs, route of administration, duration of treatment & details of invasive procedures.
7. Plan to withdraw or withhold standard therapies in the course of research.
8. Procedures for seeking & obtaining informed consent (with samples of patient information sheet & informed consent forms in English& local language.)
9. Proposed compensation & reimbursement of incidental expenses & management of research related injury /illness during & after research period.
10. Plans for publication of results -positive or negative -while maintaining the privacy &confidentiality of the study participants.

Role of basic scientist

1. Review of investigator brochure
2. Review of ICF & Protocol.

Role of social scientist

1. Review of ICF & Protocol.
2. Review design of a trial.
3. No. Of blood samples.
4. Post trial access.

Role of chairman

1. To ensure adequacy of infrastructure & facilities
2. Qualification of study team
3. Conflict of interest of ethics committee members &familyteam.
4. Plans to maintain confidentiality.
5. Vulnerable population.
6. SAE- Compensation.
7. Ongoing monitoiring by frequently visiting patients & AV recordings.
8. Ensuring training of ethics committee members.

Role of lay person

1. To ensure ethical review of the proposals ,ICF along with translations.
2. Evaluate benefits and risks from the participants perspective and opine whether benefits justify the risk.
3. Serve as a patient/participant/community representative and bring in ethical and social concerns.
4. Assess on societal aspects if any.

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