ETHICAL GUIDELINES
FOR
BIOMEDICAL RESEARCH
ON
HUMAN PARTICIPANTS

INDIAN COUNCIL OF MEDICAL RESEARCH
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REVIEW PROCEDURES

The IEC should review every research proposal on human participants before the research is initiated. 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 the justice issues.

The IEC's member-secretary or 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 review (see below for explanation).

Minimal risk would be defined as one which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current every day life.

An investigator cannot decide that her/his protocol falls in the exempted category without approval from the IEC. All proposals will be scrutinised to decide under which of the following three categories it will be considered :

1. Exemption from review

Proposals which present less than minimal risk fall under this category as may be be seen in following situations :

i. Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exceptions:

i. When research on use of educational tests, survey or interview procedures, or observation of public behavior can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or

psychosocial harm.

ii. When interviews involve direct approach or access to private papers.

2. Expedited Review

The proposals presenting no more than minimal risk to research participants may be subjected to expedited review. The Member- Secretary and the Chairperson of the IEC or designated member of the Committee or Subcommittee of the IEC may do expedited review only if the protocols involve -

1. Minor deviations from originally approved research during the period of approval (usually of one year duration).
2. Revised proposal previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
3. Research activities that involve only procedures listed in one or more of the following categories :

   a. Clinical studies of drugs and medical devices only when -

      i. research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or

      ii. adverse Event (AE) or unexpected Advcerse Drug Reaction (ADR) of minor nature is reported.

4. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.
5. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and **the same participants should not be included** in the clinical trial that may be initiated later based on the findings of the pilot study.

   a. Research on interventions in emergency situation

   When proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND) / devices / vaccine to provide emergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients -

i. when consent of person / patient / responsible relative or custodian / team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative / legal guardian when available later;

ii. when the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCGI;

iii. only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.

iv. if Data Safety Monitoring Board (DSMB) is constituted to review the data;

b. Research on disaster management

A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or state(s). It may be periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

i. Research planned tobe conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations.

ii. Disaster-affected community participation before and during the research is essential and its representative or advocate must be identified.

iii. Extra care must be taken to protect the privacy and confidentiality of participants and communities.

iv. Protection must be ensured so that only minimal additional risk is imposed.

v. The research undertaken should provide direct or indirect benefits to the participants, the disaster-affected community or future disaster- affected population and *a priori* agreement should be reached on this, whenever possible, between the community and the researcher.

vi. All international collaborative research in the disaster-affected area should be done with a local partner on equal partnership basis.

vii. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

3. Full Review

All research presenting with more than minimal risk, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable population and special groups shall be subjected to full review by all the members. While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

a. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture:
   i. from healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8 week period and frequency of collection is not more than 2 times per week;
   ii. from other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg, whichever is lesser is drawn in an 8 week period and not more than 2 times per week;
   iii. from neonates depending on the haemodynamics, body weight of the baby and other purposes not more than 10% of blood is drawn within 48 - 72 hours. If more than this amount is to be drawn it becomes a risky condition requiring infusion/blood transfusion;
   iv. prospective collection of biological specimens for research purposes by noninvasive means. For instance:
      1. skin appendages like hair and nail clippings in a non-disfiguring manner;
      2. dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth;
      3. excreta and external secretions (including sweat);
      4. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue;
      5. placenta removed at delivery;
      6. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

7. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
8. sputum collected after saline mist nebulization and bronchial lavages.

b. Collection of data through noninvasive procedures routinely employed in clinical practice. Where medical devices are employed, they must be cleared / approved for marketing, for instance -

i. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy;

ii. weighing or testing sensory acuity;

iii. magnetic resonance imaging;

iv. electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow,

v. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

c. Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.

d. Collection of data from voice, video, digital, or image recordings made for research purposes.

e. Research on individual or group characteristics or behavior not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

SUBMISSION OF APPLICATION

The researcher should submit an application in a prescribed format along with the study protocol as prescribed in SOP of IEC concerned. The protocol should include the following : -

1. The title with signature of Principal Investigator (PI) and Co-investigators as attestation for conducting the study.
2. Clear research objectives and rationale for undertaking the investigation in human participants in the light of existing knowledge.

3 Recent curriculum vitae of the Investigators indicating qualification and experience.

4. Participant recruitment procedures and brochures, if any.

5. Inclusion and exclusion criteria for entry of participants.

6. Precise description of methodology of the proposed research, including sample size (with justification), type of study design (observational, **experimental, pilot, randomized, blinded** *etc.*), intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures if any.

7.Plan to withdraw or withhold standard therapies in the course of research.

8.Plan for statistical analysis of the study.

9.Procedure for seeking and obtaining informed consent with sample of patient information sheet and informed consent forms in English and local languages.

10. Safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory, animal and human research.

11. For research involving more than minimal risk, an account of management of such risk or injury.

12. Proposed compensation and reimbursement of incidental expenses and management of research related and unrelated injury/ illness during and after research period.

13. An account of storage and maintenance of all data collected during the trial.

14. Plans for publication of results - positive or negative - while maintaining the privacy and confidentiality of the study participants.

15. A statement on probable ethical issues and steps taken to tackle the same like justification for washout of standard drug, or the use of placebo control..

16. All other relevant documents related to the study protocol like investigator's brochure for trial on drugs/ devices/ vaccines/ herbal remedies and statement of relevant regulatory clearances.

17.Agreement to comply with national and international Good Clinical Practices (GCP) protocols for clinical trials.

18. Details of Funding agency/ Sponsors and fund allocation.