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A Brief Protocol for Biomedical Research Projects

KEYWORDS

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ABSTRACT *Any biomedical research programme necessitates certain ethical issues to be addressed. All research programmes should be assessed carefully and carried out on some specific ethical guidelines. The following article discusses basic guidelines to be followed while conducting research programmes as per the guidelines laid down by the ICMR (Indian Council of Medical Research). It may direct dental postgraduate students/researchers in their study or research programmes.*

Every institution should have an Institutional Ethical Committee (IEC) comprising of a chairperson from outside the Institution, one/two persons from basic medical sciences, one or two clinicians from various institutes, one legal expert (retired judge), one social scientist (from an NGO), one ethicist, one lay person from the community and one secretary from the same institution. Minimum five people are required to form a quorum without which a decision regarding research cannot be taken.

Guidelines to be followed before undertaking any biomedical research:

Submission of Application to IEC for Review

The researcher should submit an application in a prescribed format to IEC along with the study protocol which should include the following:

1. The title of the research project with signature of Principal Investigator and Co-investigator.
2. Clear research objectives and rationale for undertaking the investigation in humans.
3. Recent curriculum-vitae of the investigators indicating qualification and experience.
4. Inclusion and exclusion criteria.
5. Precise description of methodology of the proposed research, including sample size(with justification), type of study design (observational, experimental, pilot, randomized, etc), intended intervention, dosage of drugs, route of administration, duration of treatment and details of invasive procedures.
6. Plan to withdraw or withhold standard therapies in the course of research.
7. Plan for statistical analysis.
8. Obtaining informed consent from participants in English and local languages.
9. Safety of proposed intervention to be tested including results of relevant laboratory, animal and human research.
10. Proposed compensation/ reimbursement of incidental expenses and management of research related and unrelated injury/illness during and after research period
11. An account of storage and maintenance of all data.
12. Plans for publication of result- positive/negative, while maintaining the privacy and confidentiality of the participants.
13. A statement on probable ethical issues and steps taken to tackle the same.
14. Agreement to comply with national and international Good Clinical Practices (GCP) protocols for clinical trials.
15. Details of funding agency/sponsors and fund allocation.

General Ethical Issues: The Principal Investigator is the person responsible for not only understanding research but also for observance of the rights, health and welfare of the participants. He/she should have qualification and competence in biomedical research methodology for proper conduct of the study and should be aware of and comply with the scientific, legal and ethical requirements of the study protocol.

All research involving human participants should be conducted in accordance with four basic ethical principles:

- Autonomy (Respect for person/participant).
- Beneficence.
- Non-malfeasance (do no harm)
- Justice.

Informed Consent Process

Obtaining informed consent from the participant in the human biomedical research is a must. Participants should be provided with adequate information about the research in lucid understandable language.

Information to be provided in Informed Consent Form:

1. Nature and purpose of study
2. Duration of participation with number of participants.
3. Procedures to be followed.
4. Investigations to be performed.
5. Foreseeable risks and discomforts.
6. Benefits to participants, community or medical profession.
7. Policy on compensation.
8. Alternative treatment if available
9. Steps taken for ensuring confidentiality.
10. No loss of benefit on withdrawal.
11. Benefit sharing in the event of commercialization.
12. If test for genetics and HIV is to be done, counseling for consent for testing must be given as per national guidelines.

A copy of the participant/patient information sheet should be given to the participant. The informed consent should be brief in content highlighting that it is given voluntarily after understanding the implications of risks and benefits and he/she could withdraw without loss of routine care benefits.

Obligation of Investigators Regarding Informed Consent: The investigator has the duty to:

1. Communicate to prospective participants all the information necessary for informed consent. Any restriction on participant's right to ask any questions related to the

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study will undermine the validity of informed consent.
2. Obtain from each prospective participant a signed form as an evidence of informed consent (written informed consent) preferably witnessed by a person not related to the participant. In case the participant is not competent to do so a legal guardian / authorized representative may step in.
3. Take surrogate consent from the authorized relative or legal custodian or the institutional head in the case of abandoned institutionalized individuals under judicial custody.
4. The investigator must assure prospective participants that their decision to participate or not, will not affect the patient-clinician relationship or any other benefits to which they are entitled.

Essential Information for Prospective Research Participants:
Before requesting an individual's consent to participate in research, the investigator must provide the following information in an understandable language

1. The aims and methods of the researcher.
2. The expected duration of participation.
3. The benefit that might reasonably be expected as an outcome of research to the participant or community.
4. Any alternative procedure or courses of treatment that might be as advantageous to the participant.
5. Any foreseeable risk or discomfort to the participant.
6. The extent to which confidentiality of records could be maintained, i.e. the limits to which the investigator would be able to safeguard confidentiality and the anticipated consequence of breach of confidence.
7. Free treatment for research related injury by the investigator /institution/sponsors
8. Compensation to participants.
9. Freedom of individual/family to withdraw from research any time without penalty or loss of benefits.
10. The identity of research teams and contact persons with address and phone numbers.
11. Publication, if any, including photographs and pedigree charts.

Compensation for Participation:
Participant may be paid for expenses incurred during participation in research.

Care should be taken:
1. When a guardian is asked to give consent on behalf of an incompetent person, no remuneration should be offered except a refund of out of pocket expenses.
2. When a participant is withdrawn from research for medical reasons related to the study the participant should get the benefit for full participation
3. When a participant withdraws for any other reasons, he/she should be paid an amount proportionate to the amount of participation.

Selection of Special Groups as Research Participants:
A. Pregnant and nursing women:
Pregnant or nursing women should in no circumstances be the participants of any research unless the research carried no more than minimal risk to the fetus or nursing infant and the object of research is to obtain new knowledge about the fetus, pregnancy and lactation with proper justification for the benefit and advancement in the health of pregnant or nursing women or fetus or nursing infants.

B. Children:
1. Children will not be involved in research that could be carried out equally with adult.
2. For clinical evaluation of new drugs meant for children, the study in children should always be carried out after the phase 3 clinical trials in adults. It can be studied only if the drug has therapeutic value in primary disease of the children.
3. A parent or legal guardian of each child has given proxy consent.
4. Research should be conducted in settings in which the child and parent can obtain adequate medical and psychological support.
5. The child's refusal to participate in research must always be respected unless there is no medically acceptable alternative, provided the consent has been obtained from parents/guardian.
6. The interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child participant must be justified in relation to anticipated risk involved in the study.

C. Vulnerable groups:
Efforts should be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.

1. Research on genetics should not lead to racial inequalities.
2. Persons who are economically or socially disadvantaged should not be used.
3. Rights and welfare of mentally challenged persons who are incapable of giving informed consent or those with behavioral disorders must be protected. Appropriate proxy consent from the legal guardian or parent should be taken.
4. Adequate justification is required for the involvement of participants such as prisoners, students, subordinates, and employees, service personnel etc. as research participants, since the consent provided may be under duress.

Compensation for Accidental Injury:
Research participants who suffer physical injury as a result of their participation are entitled to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability.

The sponsor (pharmaceutical company/ government/ institution), should agree, before the research begins, to provide compensation for any physical or psychological injury to the participants.

To summarize, if the basic guidelines for any research have been followed, ethical issues will not arise.