Ethical Guidelines for Human Research

S.Sheela Devi, R. Brinda Priyadarsini, Lions Aravind Institute of Community Ophthalmology, Madurai

Introduction

Medical progress is based on research, which to some extent rests on experimentation involving human subjects and/or animals. The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic and therapeutic procedures through an improved understanding of the aetiology and pathogenesis of disease. Even the best-proven theories and techniques must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality. In current medical practice and in medical research, most procedures involve some degree of risk to the subject. Hence ethical considerations are fundamental to the design of any research study involving human subjects. In India, any bio medical research has to go through a rigorous ethical process by a formal Ethical committee. Any violations of ethics will not only bar the individual from performing any human research, but also bans the institution he/she is attached to, from performing any human research. The researchers are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries This article mainly focuses the need to understand the importance of adhering to the ethical principles laid down for bio medical research.

Ethical principles governing human research:

It is very difficult to lay down ethical rules that apply to all studies uniformly in all places. It is always important to frame ethical guidelines based on each study considering its context and circumstances in which it will be conducted. The World Medical Association has prepared recommendations as principle guidelines to be adopted by every physician in biomedical research involving human subjects.

1. Competence

- Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person.
- Make appropriate use of scientific, professional, technical and administrative resources to maintain high standards of competence in the work.
- Ensure that the research question is important enough to warrant spending resources.

2. Integrity

- Investigators should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed.
- The investigators should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.
- All those involved in the research work should maintain scientific integrity and meticulous efforts are required for good quality and accurate data collection.
- Results or reports of the research should not mislead the scientific community by publishing false or deceptive statements.

3. Professional and scientific responsibility

- The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research even though the subject has given consent.
- He should consult with, refer to or co-operate with other professionals and institutions to the extent needed to serve the best interests of their patients, clients or other recipients of their services.

- Another responsibility is to standardize all the procedures involved in the process to ensure smooth functioning with minimum problems.
- Necessary approvals for the study have to be sought in advance to protect themselves against any legal issues. This includes getting approval from the Drug Controller regarding dosage of drugs to be used.

5. Respect for people's rights and dignity

- The researcher should accord appropriate respect to the fundamental rights, dignity and worth of all people.
- Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
- Legal and other obligations may lead to inconsistency and conflict with the exercise of these rights.
- Equal chance for participation - The potential benefits of research and the potential harm should be distributed equitably among communities and among individuals within communities.
- Informed consent – Essential document has to be obtained from all participants in a medical research involving human subjects. It is always the investigator's responsibility to ensure that subjects are fully informed of the potential risks and benefits of participation and the reasons it is being undertaken. Coercion and deception, even when rationalized as being for the 'greater good', are unacceptable. Full and open explanations of all study procedures to the subjects/community may be time consuming, but this is the only acceptable approach.
- Confidentiality – All information collected in the study should be maintained and only released to others with the explicit consent of all those concerned.

6. Social responsibility

- The researcher should be aware of his/her professional and scientific responsibilities to the community, the society they work and live and have to work to mitigate the causes of human suffering.

Institutional code of research ethics

The institution should create and maintain an environment with adequate support systems to enable researchers to follow ethical guidelines. To promote scientific research studies it is always better for the institution to have their code of research ethics to facilitate the research activities. It has the responsibility to respect the autonomy of researchers while adhering to the ethical guidelines for research. The Institutional code for research should have the following:

- The institutional code for research should provide guidelines for conducting research activities with highest standards of ethical and scientific practice.
- It should fix norms for research projects selection and to be conducted adhering to the institutional policies for research and financial policies.
- Specific and clear guidelines regarding management of data and publications should be laid down.
- Institutional policy in case of any problem of misconduct with regard to ethics in research should be laid down.

Institutional review board:(IRB)

Institutions undertaking research should constitute their own IRB consisting Faculty Researchers, clinical staff, patient advocates, lay members and persons knowledgeable about legal and ethical issues concerning research. The IRB policies should be laid down in a way, which should protect subjects of the research and assist with designing consent forms. Any research study undertaken by the institution should get the approval from the IRB. Even though the research is approved by the IRB, it does not guarantee that research is ethically accepted, because it place more emphasis on consent forms and on the risk and benefits of research than on other ethical issues. Also IRB is unable to monitor whether the research is carried out in accordance with the protocol. IRB approval should be regarded as a minimal ethical standard for research. The most important factor for assuring that research is ethically acceptable is the judgment and character of the researcher. IRB has a vital role in protecting the public and facilitating useful research.

Conclusion

The new advances in science and medicine are a cause for celebration, at the same time it needs careful evaluation of risk benefit. It is imperative to incorporate all the specific guidelines for biomedical research that are provided from time to time, taking into consideration all the new and changing dimensions. Recent cases of fraud in bio medical research, with wholesale fabrication of data, have dramatized how difficult it may be to detect even blatantly unethical research practices. It certainly affects other researchers/institutions who maintain integrity and professionalism in their research study. Ultimately the protection of subjects in any research study lies in the scrupulousness, conscience and personal integrity of the investigator. If not, no amount of red tape or code or committee can be an adequate safeguard for the individual.

Ethical consideration on human research at a glimpse

- Written protocol of the research study
- Approval from the IRB
- Approval from Council for Medical research
- Approval from the Drug Controller for the Intervention
- Informed consent from the subjects
- Accuracy in data collection
- Confidentiality in Data management
- Regular potency checks of the intervention
- Information regarding Potential benefits and risks and its management

Suggested Reading

1. *Ethical guidelines for Biomedical research on human subjects*.ICMR Bulletin, Vol.30, No.10: October 2000
2. Stephen B Culley, Stephen R Cummings. *Designing Clinical Research*
3. Peter G Smith , Richard H.Morrow. *Field Trials of Health Interventions in Developing Countries*
4. *Booklet on Ethics from All India Ophthalmological Society,* 1999-2001