

ETHICS IN RESEARCH

R Kanungo

Research in biomedical science in India has undergone a sea change in the recent years. Globalization, free market and easy access to information, have contributed to this change. Research and publications have gained importance now more than ever before. Increasing research facilities and availability of state of the art equipment have opened up exciting avenues for scientists in the field of medical research. The West is looking at India as a gold mine for clinical trials. Cloning and Stem cell research have hit the headlines with tremendous potential for therapeutic use. However there is a nagging fear that in the pursuit of research, ethical practices have not kept pace. Frequently these issues are taken by the media, to the discomfort of the scientific community. In most cases noncompliance to ethical guidelines, is more out of ignorance than deliberate omission and in some, intense pressure to publish for continuance in positions of repute.

History reveals numerous unethical practices in research. To establish supremacy of the Aryan race in Germany during Hitler's regime, large population were sterilized by intrauterine injection of silver nitrate during routine physical examination without informing the women. Typhus vaccine was tried in prisoners in Buchenwald concentration camp. They were given vaccine or placebo and then injected with blood from patients with typhus fever. The organisms were maintained in prisoners who served as "passage groups". These experiments were uncovered during World War II. The Nuremberg trial exposed to the world the atrocities practiced in the Nazi concentration camps during Hitler's regime. Tuskegee Syphilis Trial in Alabama, is the longest clinical trial undertaken among the poor African American share croppers, who were denied treatment, just so that the natural course of syphilis could be documented. No informed consent was taken (in fact they were misinformed that they were receiving free health care). Death rate was reported to be twice as high as controls after 10 years of study. Penicillin which came into use in 1942 was denied to these subjects. This study was stopped in 1972 when reports started appearing in the press.

We are aware of the Thalidomide tragedy. In 1950 this drug was approved for OTC sales in Europe, Japan, Australia, Canada and Brazil. The German manufacturers of this drug had not collected human safety data before releasing it to the market. Clinical trials in pregnant women and animal studies

were started simultaneously in the US. Shortly after the beginning of the trial Australian, American and European physicians started reporting large number of birth defects by 1961. Over 8000 children were born without hands and legs. Deception in research was reported in the Milgram study. Stanley Milgram's research on Holocaust people's response to authority, where the subjects, who were not fully informed of the study modality, were made to carry out certain activities without comprehending the implications. This encroached upon the psychological domain of the participants.¹

These are some of the events which spurred the world to lay down certain guidelines for ethics in research. First global document was the Nuremberg code emphasizing voluntariness and consent in participation. Ten conditions were laid down. These included guidelines for: a) voluntary participation, b) consent by the participant, c) research which should benefit society, d.) study design which must be based on prior animal experiments e). avoidance of physical and mental suffering to the subject, f). avoiding experiments where there was prior reason to believe that death or disability could result from the study g) degree of experiment which should not exceed limit determined by humanitarian importance of the problem, h.) protecting the participant against injury i.) requirement of scientifically qualified person to conduct research j) to bring experiment to an end and stop if any danger is perceived to the patient. These guidelines formed the foundation for subsequent code of conduct for undertaking research.

The data gathered from the holocaust experiments have not been used by the scientific community. Questionable and unethical methods were adopted in these experiments.

In recent times too there have been reports of unethical research practices. A shocking revelation of scientific fraud in stem cell research came to the lime light as recently as December 2005. Studies of stem cell research and possibly cloning carried out by Hwang Woo Suk from Seoul National University published in *Science* (June 2005) have come under scrutiny for unethical practice and data fabrication.

World Medical Association— the first body of doctors, laid down guidelines in 1964, geared especially for doctors, under the Helsinki declaration. This addresses the conflict which arises when doctors conduct research on their patients. These are based on three principles. First being respect for the research subject, second principle stresses on beneficence and the third on justice. The Council for International Organisation of Medical Sciences (CIOMS) laid down

*Corresponding author (email: <rebakanungo2001@yahoo.com>)
Department of Clinical Microbiology, Pondicherry Institute of Medical Sciences, Pondicherry-605 014, India.

principles for biomedical research, particularly for developing countries (as documented in the declaration of Helsinki).

Indian Council of Medical Research (ICMR) released a “Policy Statement on Ethical Considerations Involved in Research on Human Subjects” in 1980 in India. “Ethical Guidelines for Biomedical Research” is the updated document released in 2000.²

While conducting human research the investigator systematically develops, designs, and executes methods to contribute to the knowledge about individuals or groups. While doing so, the professional or student (researcher) documents information through intervention, interaction or by gathering personal information.

It is expected, (if not mandatory) to follow ethical guidelines while carrying out any type of research involving human subjects. Researchers need to be aware of ethical issues relating to informed consent, compensation for participation, confidentiality, publication practices and international collaboration.³ There are guidelines regarding inclusion of vulnerable groups especially student volunteers. Voluntary participation without coercion has to be borne in mind by researchers in the faculty while carrying out studies on student population. Selection of special vulnerable groups as study subjects including mentally challenged, pregnant women and economically weak are of special concern.

Research in the form of dissertations, thesis, and scientific projects are part of most postgraduate curriculum in teaching institutes. A student very often embarks upon a research activity involving human subjects without the knowledge of ethical principles. It will surprise many that as microbiologists involved in basic research confined to the laboratory, adherence to ethical practice is as important as it is for any other person in the medical fraternity. A simple (as it may seem) activity of collecting sputum or feces for examination purely for the purpose of research, other than routine diagnosis, requires an informed consent from the subject.

Ethical issues are involved in carrying out investigations related to HIV screening, evaluation and sociological studies. The other area of concern is in conducting case control studies involving healthy individuals for interventional analysis.

Publication of research data must adhere to predetermined authorship guidelines.⁴ Conflict of interest of participating groups must be kept in mind before submission of manuscripts for publication. Some peer reviewed scientific journals require information on specific inputs by the authors of a research paper. Plagiarism and lifting of scientific information without citing the source are maladies afflicting research publications.

All extramural funding agencies whether National or International lay down strict guidelines for compliance. Many research projects, with good scientific content, get rejected on ethical grounds by review boards of institutions or funding agencies. Education and timely orientation of students to ethical issues and guidelines prior to taking up research projects will reduce delays and rejections from research and funding agencies.

References

1. Committee on Human Research Training Module: Johns Hopkins Bloomberg School of Public Health, Baltimore, MD.(http://www.jhsph.edu/chr_acc12.12.05).
2. Central Ethics Committee on Human Research (CECHR):Ethical Guidelines for Biomedical Research on Human Subjects: Indian Council of Medical Research. 2000.
3. Good Clinical Practices for Clinical Research in India.2001. Central Drugs Standard Control Organisation (DGHS, Ministry of Health and Family Welfare, Govt of India) Manual of National Workshop on Good Clinical Practices and Regulatory Requirements for Clinical Trials in India. Dept.of Clinical Pharmacology,TN Medical College and BYL Nair Hospital. Mumbai.2005.
4. Good Clinical Practice for Ethics Committee Members: Manual WHO Sponsored Workshop. Department of Pharmacology, JIPMER 2005.