RESEARCH ETHICS COMMITTEES (RECs) AND MONITORING OF BIOMEDICAL RESEARCH IN PAKISTAN

Akhtar Sherin[1]✉

[1]✉ Managing Editor: Khyber Medical University Journal, Khyber Medical University Instituite of Medical Sciences (KIMS)
DHQ Teaching Hospital KDA Kohat, Pakistan
E mail: kmuj@kmu.edu.pk, akhtarsherin@yahoo.com

THIS ARTICLE MAY BE CITED AS: Sherin A. Research ethics committees (RECs) and monitoring of biomedical research in Pakistan. Khyber Med Univ J 2013; 5(3): 121-122.

Global health is facing enormous challenges and medical research is the only way to cope with these challenges. Worldwide, extensive clinical research is being conducted in all fields of medicine to resolve the health related issues through best available evidence. Any research on health intervention will need clinical trials on human beings. However, human exposure to any prophylactic, diagnostic or therapeutic interventions may lead to potential detrimental effects on human health. This is a serious ethical issue as the health of individuals participating in any research cannot be compromised and every effort should be made to safeguard the health and rights of the participating subjects.

The history of ethics violation as well as the efforts to regulate medical research on human being is quite old. However it was in 1947, when Nuremberg (United States) military tribunals pronounced a verdict on the criminal trial of German physicians for violating ethics during research on human participants. The verdict also recommended 10 conditions for medical experiments, laying out basic principles for medical research, commonly known as Nuremberg code.[1] Issues like voluntary informed consent, right to withdraw consent; prior research on animals, risk benefit ratio, likelihood of favourable results, premature stopping of trial in case of harmful results and research by the experienced personals were the hallmark of Nuremberg code. This historic document was the foundation of declaration of Helsinki, which was adopted by the 18th general assembly of world medical association (WMA) at Helsinki, Finland in 1964 and later on amended several times.[2] Declaration of Helsinki has laid down the ethical principles for physicians to conduct medical research on human beings. It emphasized the role of research ethics committee (REC) and it was made obligatory to get the research protocol reviewed and approved by REC before starting the study. In 1967, the first REC in United Kingdom was established when Royal College of Physicians of London recommended to observe ethical supervision of clinical research in institutions of UK.[3] In USA, the controversy of Tuskegee syphilis study (1932-1972)[4] led to the national research act of 1974, establishing the national commission for the protection of human subjects of biomedical and behavioral research.[5] This commission published its report, commonly known as Belmont report[6] on 30 September 1978. This important document laid down the basic ethical principles (respect for persons, beneficence, and justice) for research involving human beings and also identified primary areas of application of these general principles in the conduct of research (informed consent, assessment of risks and benefits, and selection of subjects). Since then, research on humans is being regulated by the RECs and institutional review boards for bioethics (IRBB) in all major developed countries, across the globe.

However, research in developing countries is not being practised as per international ethical standards.[7] Local research is not properly monitored for the ethical violations. Due to lack of the research opportunities, researchers of the developing countries are more attracted towards participation in international collaborative trials. The benefits of collaborative clinical trials like the issues of augmented patient enrolment specially in rare diseases, rapid completion of the trial, diversity of the patients recruited and cost effectiveness cannot be denied.[8] However, the multinational trials sponsored by the developed countries recruiting patients from developing countries are not following the ethical norms as per their own countries and various ethical malpractices have been reported.[9,10] The council for the international organization of medical sciences (CIOMS) developed and published ethics guidelines for biomedical research involving human subjects in developing countries. These guidelines, issued in 1982 and updated in 1993 and 2002, were particularly prepared to address the issue and needs of low-resource countries and to regulate multinational/ multi-centred collaborative research.[11] These guidelines were reviewed in 2004 by Islamic organization of medical sciences (IOMS) and Islamic perspective was added to it.[12]

In Pakistan, the situation is not very different from any other developing country. Although a few research ethics committees existed in individual institutions, there was no serious effort at the government level to monitor the clinical

research in Pakistan till 2004. Pakistan Medical Research Council (PMRC) constituted the National Bioethics Committee (NBC) which was approved by ministry of health, government of Pakistan and notified on January 28, 2004.[13] This advisory body was given the mandate to deal with bioethical issue in health services delivery, health research, health education and medical journalism in Pakistan and to serve as "umbrella body" for other institutional ethics review committees. Right from the start, this committee remained dormant and the first meeting of NBC was held after 28 months when the members had almost completed their turn.[14] Although, NBC developed local guidelines for reviewing the research projects involving human subjects in Pakistan,[15] the overall role of NBC in ethical regulation of clinical research and its role as "umbrella body" is not worth appreciating.

Due to mandatory requirement of REC/IRBB approval certificate by many journals for publication of the manuscripts, increased multinational collaborative research participation from Pakistan, boosted awareness regarding bioethics among the researchers and dedicated efforts of various organizations, the number of RECs and IRBBs has risen sharply. However, there is no apical body to register, accredit or monitor the RECs and IRBBs in Pakistan. After the 18th amendment to the constitution of Pakistan, more autonomy has been vested to the provinces but so far there is no provincial authority or monitory body to regulate the clinical research on human beings. The drug regulatory authority of Pakistan (DRAP) has been established in 2012, but its role is limited to drug registration and licensing of drug manufacturing units. There are no legal penalties or sanctions for doing research without ethical approval or for violating the safety protocol, REC decision and recommendations. Research protocols are reviewed and granted approval by RECs but serious flaws and inconsistency in the review process, compromised autonomy of RECs, lack of review and monitoring of the on-going studies for adherence to the approved protocol, dearth of power of independent data monitoring teams for premature termination/ suspension of any clinical research due to safety concerns are the critical issues in monitoring biomedical research in Pakistan. Government authorities need to take serious notice of the situation and take extraordinary, appropriate measures for establishing the credibility and integrity of the RECs in Pakistan. Failing to do so will lead to relegating RECs/ IRBBs in Pakistan to "being no more than rubber stamping committees".[16]

REFERENCES

1. Trials of war criminals before the Nuremberg military tribunals under control council law no. 10. Nuremberg, October 1946–April 1949. Washington, D.C.: U.S. G.P.O, 1949–1953.
2. World Medical Association. World medical association declaration of Helsinki: Ethical principles for medical research involving human subjects. Available from URL: http://www.wma.net/en/30publications/10policies/b3/17c.pdf (Cited on June 01, 2013).
3. Royal College of Physicians. Supervision of the ethics of clinical research investigations in institutions. London: HMSO, 1967.
4. Curran WJ. The Tuskegee syphilis study. N Engl J Med 1973; 289(14):730-1.
5. Legislative history of title II-protection of human subjects of biomedical and behavioral research of the National Research Act, PL 93-348. Available from URL: http://history.nih.gov/research/downloads/PL93-348.pdf (Cited on June 01, 2013).
6. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. DHEW Publication No. (OS) 78-0012. Available from URL: http://videocast.nih.gov/pdf/ohrp_belmont_report.pdf (Cited on June 01, 2013).
7. Ana J, Koehlmoos T, Smith R, Yan LL: Research misconduct in low- and middle-income countries. PLoS Med 2013, 10(3):e1001315.
8. Moss AJ, Francis CW, Ryan D. Collaborative Clinical Trials. N Engl J Med 2011; 364:789-91.
9. Angell M. The ethics of clinical research in the third world. New England J Med 1997;337:847-9.
10. Mudur G. Johns Hopkins admits scientist used Indian patients as guinea pigs. Br Med J 2001;323:1204.3
11. The Council for International Organizations of Medical Sciences (CIOMS). International Ethical Guidelines for Biomedical Research Involving Human Subjects. CIOMS, Geneva 2002. Available from URL: http://www.cioms.ch/publications/guidelines/guidelines_nov_2002_blurb.htm (Cited on June 02, 2013).
12. Islamic Organization for Medical Sciences. International ethical guidelines for biomedical research involving human subjects "an Islamic perspective." In El-Gendy AR, Al-Awadi ARA, editors. The international Islamic code for medical and health ethics. Kuwait: Islamic Organization for Medical Sciences; 2005:Vol 2, 121-276.
13. Pakistan Medical Research Council. National Bioethics Committee (NBC). http://www.pmrc.org.pk/NBC%20Guidelines.htm (Cited on June 02, 2013).
14. Pulse Pakistan. National Bioethics Committee meets at last after 28 months. Professional Medical Publications. August 15-31, 2009. Available from URL: http://www.pulsepakistan.com/archives/15-08_09/news7.htm (Cited on June 02, 2013).
15. Pakistan Medical Research Council. National Bioethics Committee Pakistan, Ethical Research Committee-Guidelines. Pak Med Res Counc. (Online): Available from URL: http://www.pmrc.org.pk/erc_guidelines.htm(Cited on June 02, 2013).
16. Jafarey AM, Iqbal SP, Mariam Hassan M. Ethical review in Pakistan: the credibility gap. J Pak Med Assoc 2012;62(12):1354-7.

KMUJ web address: www.kmuj.kmu.edu.pk
Email address: kmuj@kmu.edu.pk