EDITORIAL

RESEARCH ETHICS NEED CONSIDERATION

Abdul Rashid, Muhammad Ayub, Mohammad Salim Wazir

Department of Pharmacology, *Physiology, **Community Medicine, Ayub Medical College, Abbottabad, Pakistan

Objectives of medical research include developing knowledge that could be generalised to increase understanding of biomedical subjects with the ultimate goal of improving health of the population.[1] In the past century, research has contributed to identifying many risk factors causing miseries for human populations and has been instrumental in decreasing the morbidity and mortality due to many diseases. Many vaccines, drugs, and other diagnostic and therapeutic procedures were approved after evidence created by researchers through their tireless efforts. However, there is a risk of exploitation of human subjects enrolled in research projects especially those with interventional designs.[2]

The history of medical ethics dates back to Hippocrates who merged ethics, a branch of philosophy, with medicine. The real emphasis on medical ethics concerning research emanated from the Nuremberg trial necessitated by the unabated and ruthless experiments on human subjects in Nazi concentration camps having state patronage. These experiments were not only physically brutal but also had little respect for human dignity in the quest of looking for the attributes of a so-called best race on earth.[3] After the Nuremberg Code, the World Medical Association (WMA) that came into being in 1947 as the international organization that seeks to represent all physicians, regardless of nationality or specialty. The WMA has the role of establishing general standards in medical ethics that are applicable worldwide. The WMA has worked to prevent any recurrence of the unethical conduct exhibited by physicians in Nazi Germany and elsewhere. The WMA updated the Hippocratic Oath for 20th century use through the Declaration of Geneva, adopted at the WMA's 2nd General Assembly in 1948. The Oath has been revised several times since, most recently in 2006. Besides developing International Code of Medical Ethics, it also developed ethical guidelines for research on human subjects. The final draft of such guidelines took a decade and a half and was adopted as the Declaration of Helsinki in 1964.[4] This document has also undergone periodic revision, most recently in 2008 in the 59th WMA General Assembly held at Seoul, Korea.[5]

Based on these, universities, colleges, and professional organizations have developed ethical guidelines for research that are updated from time to time. This has resulted in the establishment of Institutional Ethical Review Boards in all institutions carrying out research through different study designs. Dissertations, theses, and other research projects undergo reviews at planning, implementation, and reporting stages. Funding agencies also ask for approval of projects from such committees/boards. Moreover, medical journals also require such certification that is rigorously implemented especially in the developed countries. International Committee of Medical Journal Editors (ICMJE) also requires that ethical approval should be obtained and published. Over 500 journals now follow these guidelines of ICMJE. Though there are guidelines at all levels, it is a matter of concern that implementation of such guidelines is below expectations seen in the light of the spirit of Nuremberg Code and Helsinki Declaration. It would be expected that they might not be followed in letter and spirit in under developed and developing countries but in reality the developed countries also lag behind in following these codes. Even in a country like United States, five medical journals that were studied were found deficient in reporting ethical approval. Though ethical approval was reported in 97% cases of randomised controlled trials (RCT), but in the case of other study designs it was found to be on the lower side.[6]

Most of the researchers consider obtaining consent synonymous with ethics. Research ethics, however, go beyond consents. Privacy and confidentiality are universal contents of consents and need to be followed. Benchmarks need to be developed at every level with operational principles identified in a perspective by Emanuel *et al* as: 'collaborative partnership, social values, scientific validity, fair selection of study population, favourable risk-benefit ratio, independent review, informed consent, and respect for recruited participants and study communities'.[7]

These principles need to be adhered to in the light of the widely known principles of medical ethics: autonomy, beneficence, non-maleficence, and justice. Institutional Review Boards need to include qualified and scrupulous people to develop proper guidelines with rigorous enforcement. The Institutional Review Boards and Committees should not only review the projects at planning level but also at implementation and reporting levels. The medical journals include guidelines for authors how to write their manuscripts. Unfortunately many journals do not include guidelines regarding ethics on research. It

is imperative that medical journals include proper guidelines in this regard and shall be rated for inclusion of guidelines and reporting of ethical approval of relevant boards. In this way the journals would contribute meaningfully in upholding the universal principles of ethics.

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Address for Correspondence:

Dr. Mohammad Salim Wazir, Department of Community Medicine, Ayub Medical College, Abbottabad-22040, Pakistan.
Email: salimwazir@ayubmed.edu.pk