EDITORIAL

Ethical Principles in Research Involving Human Health

Akter S[1], Al-Mahmood AK[2], Alsharkawy A[3], Zakaria H[4], Zainol J[5], Salam A[6].

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INTRODUCTION

Research involving human health or medical research is the scientific study on both medical and behavioural aspects relating to human health aimed to improve the health and well-being of everyone[1]. The ethical principles in research are guided by documents like the Belmont Report, the Declaration of Helsinki developed by World Medical Association (WMA)[3], and Council for International Organizations of Medical Sciences (CIOMS) guidelines[4]. They ensure that research respects human rights while advancing science responsibly. The WMA (2025), emphasizes the physicians' fundamental duty to prioritize the health, well-being, and rights of patients in all aspects of their care, including their involvement in medical research. Physicians are obliged to use their knowledge and ethical conscience to accomplish this duty[3].

Following the ethical principles, the research ensures the integrity and honesty of the research results. Moreover, it prevents participants from being exploited or treated unfairly by the research team[5]. The Belmont Report articulated three foundational principles: respect for persons, beneficence, and justice[3]. Modern clinical ethics upholds four key ethical principles: autonomy, beneficence, non-maleficence, and justice[6,7].

Key principles in ethics

Autonomy: It refers to respect for participants and their rights. The key aspects of patient autonomy include informed consent, truth telling, confidentiality, patient self-determination and support for patient-centered care. The participant must be competent to understand and decide, and they should be provided with all necessary information which are free, informed, and comprehended, so that they can make their own informed decisions voluntarily. Throughout the whole research, confidentiality and privacy of the participants to be protected[7]. The informed consent process has three components: information, comprehension, and voluntariness. A good patient-physician communication ensures an effective inform consent through an effective communication[8,9]. The Belmont report emphasizes the information to be presented clearly, in an understandable manner, and with sufficient time for the subject to ask questions. For higher-risk studies, the process requires more rigorous efforts to confirm comprehension such as some level of questioning the participant or even getting written responses to questions to ensure their understanding is appropriate[10]. Where the participant is incapable to give consent as in case of infants and children below 18 years and incompetent individuals due to developmental,

1. Shaima Akter, Senior Clinical Fellow in Medicine, Ashford and St. Peter's Hospitals, NHS Foundation Trust, Surrey, UK.
2. Abu Kholdun Al-Mahmood, Chief Editor, International Journal of Human and Health Sciences (IJHHS), Professor and Head of the Department of Biochemistry, Ibn Sina Medical College, Dhaka, Bangladesh.
3. Alsyed Alsharkawy, Paediatric Unit, Faculty of Medicine, Widad University College (WUC), Kuantan, Pahang, Malaysia.
4. Hasbullani Zakaria, Biochemistry Unit, Faculty of Medicine and Deputy Vice Chancellor (Research & Postgraduate), WUC, Kuantan, Malaysia
5. Jamaludin Zainol, Professor of Surgery and Dean, Faculty of Medicine and Deputy Vice Chancellor (Academic and Internationalization), WUC, Kuantan, Pahang, Malaysia.
6. Abdus Salam, Medical Educationalist and Public Health Specialist, Faculty of Medicine, WUC, Kuantan, Pahang, Malaysia.

Correspondence to: Dr Abdus Salam, Associate Professor and Head of Medical Education Unit, Faculty of Medicine, Widad University College, Bandar Indera Mahkota (BIM), 25200 Kuantan, Pahang, Malaysia. Email: abdussalam.dr@gmail.com

mental or physical disorder, the physician should seek informed consent from the legally authorized guardian. However, in conditions of absence of legally authorized person, and the research cannot be delayed, the study may proceed without informed consent provided the specific reasons of inability in obtaining informed consent are documented in the research protocol and the study is approved by a research ethics committee with consent to continue sought as soon as possible[1,3]. Special care to be taken in including vulnerable groups (e.g. children, disabled). Such research including a vulnerable group is justified if it addresses the specific health needs of this group and the research cannot be conducted in a nonvulnerable group and the study is beneficial to this group[3,5].

Beneficence: The principles of beneficence include the obligation of physicians to maximize potential benefits of the patient and minimize harm. Risks must be justified by the value of the knowledge gained. The principle of beneficence calls for not just avoiding harm, but also to benefit patients and to promote their welfare[3,7].

Non-Maleficence: This is the obligation of physicians to avoid causing physical, psychological, or social harm to participants. Avoiding harm requires scientifically sound design, vigilant safety monitoring, and prompt management of adverse events. The practical application of non-maleficence is for the physician to weigh the benefits against burdens of all interventions and treatments, to avoid those that are inappropriately burdensome, and to choose the best course of action for the patient[3,7].

Justice: Justice emphasizes fair, equitable, and appropriate distribution of research benefits and burdens among participants. Justice requires avoiding exploitation by ensuring participants are not unduly disadvantaged due to poverty or urgency. Ethical recruitment should not target vulnerable populations for convenience but reflect the scientific purpose of the study[11].

Independent Review

All studies involving humans must undergo ethical review and approval by an independent Research Ethics Committee (REC) or Institutional Review Board (IRB) to ensure that proposed protocol meets the appropriate ethical guidelines before subject enrolment in the study[10]. Research protocols must describe risk–benefit assessments, consent procedures, privacy protections, compensation/treatment for research related harm, and for clinical trials, must describe any post-trial provisions[3].

Cultural Context

The four principles of medical ethics are universally acknowledged; however, they are affected by varying cultural, social, and institutional factors in different regions influencing the perceptions of health, decision-making processes, doctor-patient relationships, and the fair distribution of resources[11]. For example, in many Asian cultures, family members are actively involved in medical decisions, especially for elderly people[12]. However, in Western countries, patient autonomy is the priority[11] Similarly, favouritism or differential treatment of patients based on their wealth, income, socioeconomic status violates the principle of justice directly correlate with access to quality healthcare, creating disparities that violate this principle[11]. Moreover, in Asian context, ethical dilemmas exist in areas such as reproductive health care, addiction treatment and vaccination policies[11].

CONCLUSION

This paper highlights the core ethical principle in human health or medical research. The main ethical principles in human health or medical research include: autonomy, beneficence, non-maleficence, and justice. Ethical excellence in medical research is achieved through informed, voluntary participation and fair distribution of research burdens and benefits. However, there is variation based on the cultural, social, and institutional factors. Therefore, cultural context must be considered while taking the ethical decisions.

Conflict of interest

The authors have no conflict of interest to declare.

Authors contribution

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REFERENCES

1 Avasthi A, Ghosh A, Sarkar S, Grover S. Ethics in medical research: General principles with special reference to psychiatry research. *Indian J Psychiatry* 2013;55(1):86-91. doi: 10.4103/0019-5545.105525.

2 OHRP. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. U.S. Department of Health & Human Services; *Office for Human Research Protections* (OHRP). 1979. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report.

3 WMA. World Medical Association (WMA) Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Participants. *JAMA* 2025;333(1):71–74. doi:10.1001/jama.2024.21972.

4 CIOMS. International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva. *Council for International Organizations of Medical Sciences* (CIOMS); 2016.

5 Masic I, Hodzic A, Mulic S. Ethics in medical research and publication. *Int J Prev Med* 2014;5(9):1073-82.

6 Akter S, Salam MM, Yousuf R, Al-Mahmood AK, Salam A. Ethical Principles in Medicine: A Deeper Reflection on Autonomy, Beneficence, Nonmaleficence, and Justice in Current Medical Practice. *International J Human and Health Sciences* 2025;09(03):139-142. doi: http://dx.doi.org/10.31344/ijhhs.v9i3.834

7 Varkey B. Principles of Clinical Ethics and Their Application to Practice. *Med Princ Pract* 2021;30(1):17-28. doi: 10.1159/000509119.

8 Yousuf R, Alsharkawy A, Salam MM, Akter S, Pasha MA5, Begum H, Salam A. The Key to Communication Skills in the Patient-Physician Relationship. *International J Human and Health Sciences* 2024; 08(04): 305-309. doi: http://dx.doi.org/10.31344/ijhhs.v8i4.727.

9 Salam A, Zakaria H, Abdelhalim AT, Choon LC, Alsharkawy A, Taibi MKBM, Satwi S, Hassan KM, Zainol J. Communication Skills of Fresh Medical Graduates in a Malaysian Private University. *Bangladesh J Med Science* 2022;21(02):404-412. doi: http://doi.org/10.3329/bjms.v21i2.58074

10 White MG. Why Human Subjects Research Protection is Important. *Ochsner J* 2020;20(1):16-33. doi: 10.31486/toj.20.5012.

11 Kaczmarek A, ¯ok A and Baum E. Ethical principles across countries: does 'ethical' mean the same everywhere? *Front. Public Health 2025;* 13:1579778. doi: 10.3389/fpubh.2025.1579778.

12 Xu H, Yuan M. Family roles in informed consent from the perspective of young Chinese doctors: A questionnaire study. *BMC Medical Ethics* 2024; 25:2. https://doi.org/10.1186/s12910-023-00999-6.