

## The Evolution of Ethical Standards in Health Research: An Islamic Overview

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**Abstract:** *This review examines the intricate historical route of ethical standards within health research, integrating insights from an Islamic perspective. It meticulously traces pivotal junctures from the genesis of ethical frameworks like the Nuremberg Code and the Declaration of Helsinki to the establishment and evolution of Institutional Review Boards (IRBs). Employing content analysis, the paper examines the adaptive nature of ethical guidelines in facing contemporary challenges, including genetic research and emerging technologies, through the lens of Islamic principles. It emphasizes the dynamic interplay between ethics and progress, highlighting the pivotal role of ethical considerations in safeguarding the well-being of research participants and upholding the integrity of scientific endeavours within an Islamic ethical framework. Through this exploration, the study underscores the indispensable role of ethical foundations in steering responsible and socially conscious research practices across multifaceted domains, thereby shaping a more conscientious and accountable landscape in health research, enriched by Islamic perspectives.*

**Keywords:** *consent, ethical, standard, evolution, health, research, Islamic overview*

### INTRODUCTION

Research ethics encompasses moral considerations at every stage of research, including planning, execution, and dissemination. It extends beyond protecting the rights of human and animal subjects and includes aspects such as data handling, reporting, researcher interactions, and resolving disputes. The primary aim is to ensure that research benefits the public, subjects, and researchers themselves [1]. Traditionally, the medical field has drawn ethical principles from the Hippocratic Oath, emphasizing the duty of care and "Do no harm" principle. However, as medicine evolved and democratization reshaped doctor-patient relationships, questions arose about the oath's adequacy. Nonetheless, many still see it as embodying a physician's core virtues and responsibilities towards patients or research participants [2].

"Ethical guidelines" are documents aiding individuals in adhering to ethical principles and practices. Research ethics committees, also known as ethical review boards (ERBs), are responsible for reviewing research protocols involving human participants, ensuring adherence to ethical principles. This oversight covers various research activities involving human interaction, data collection, or analysis aimed at generating new knowledge [3].

These committees play a crucial role in upholding global and local ethical standards for research involving human participants, from proposal to completion. They also address ongoing ethical concerns and align their review processes with international standards and local laws. Involving children and young individuals in research raises ethical concerns regarding comprehension, consent, external pressures, and conflicts of interest. Understanding developmental stages is crucial for determining consent requirements and engaging them appropriately in research discussions [4].

Research ethics committees play a vital role in safeguarding potential participants and evaluating risks and benefits to the community. They ensure high ethical standards in health research, often required for publication in medical journals.

## LITERATURE REVIEW

In exploring the historical development of ethical norms in health research, a thorough literature review was conducted, encompassing historical records, research articles, books, and scholarly publications. Emphasis was placed on significant milestones including the Nuremberg Code, the Declaration of Helsinki, and the establishment of Institutional Review Boards (IRBs). Additionally, Islamic literature was reviewed to offer insights into ethical considerations within the broader context of research ethics evolution, highlighting Islamic principles that underpin ethical conduct in research. These documents and historical texts provided valuable insights into the evolution of research ethics and instances of ethical lapses.

Coughlin delves into the ethical dimensions of epidemiologic research and public health practices, showcasing conceptual frameworks, historical perspectives, and critical topics in the field [5]. Notably, the International Ethical Guidelines for Epidemiological Studies, developed by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), cover a broad spectrum of ethical considerations in research, including informed consent, vulnerable populations, and the use of technology and biological samples [6].

National Health and Medical Research Council Examines the ethical complexities in involving children and young individuals in research, the National Statement on Ethical Conduct in Human Research provides a structured guide for researchers, ethical review bodies, and research governance bodies. Its sections emphasize overarching values, risk assessment, consent, design considerations, participant-specific ethical concerns, and governance processes.

Hedgecoe presents historical accounts that shed light on the establishment of Research Ethics Committees (RECs) in the UK during the late 1960s and early 1970s, underscoring the Ministry of Health's pivotal role in shaping the interpretation of recommendations while maintaining these committees' advisory nature [7]. In addition, Hoeyer, Dahlager & Lynøe discuss the conflicting ethical paradigms between social scientists and medical researchers highlight tensions, particularly regarding patient perceptions, roles of medical staff, informed consent challenges, and data ownership.

The article by Talukder et al emphasizes the necessity of Institutional Ethical Review Boards (IERBs) in Bangladesh for ethical clearance in biomedical research involving human participants [8]. Mohamed, Shitindo, & Gasch focus into the historical context of research ethics violations in Africa, advocating for equity, local capacity building in bioethics, and the application of bio-ethical principles to address emerging challenges [9]. The Council of Europe's guide provides comprehensive insights into the role of Research Ethics Committees (RECs) in reviewing biomedical research proposals involving humans, emphasizing their pivotal role in ensuring ethical standards, scientific quality, and conformity with national laws [10].

Kim's exploration into ethical issues in clinical research illustrates the evolution of ethical guidelines following historical scandals. This review emphasizes the responsibilities of institutions and investigators in ensuring the safety and welfare of research subjects while outlining contentious ethical matters for Institutional Review Boards (IRBs) to address [11]. The module "Introduction to Research Ethics" contextualizes ethical decision-making in research involving human participants, integrating historical and legal perspectives alongside national and international ethical guidelines [12].

Mina, Pooneh, and Bagher discuss the importance of ethically sound pediatric trials and legislative attempts to compile guidelines. They address challenges in informed consent and risk-benefit assessment due to variations in religious and socio-cultural contexts, proposing an Islamic approach to address these concerns [13]. Zulfiqar explores the role of research in addressing health disparities. He underscores the necessity of adhering to ethical principles and advocates for greater discourse on indigenously sponsored research, particularly in public health contexts [14].

Saleem and Sumaya underscore the foundational monotheistic principles of Islam and their relevance to medical ethics. They emphasize the significance of consensus-based decision-making and cultural sensitivity in treatment to assist physicians in better understanding Muslim patients. AlFattani and AlAlem delve into the impact of religious beliefs on medical research involving children. They advocate for the development of culturally adapted ethical guidelines that align with Islamic principles [15]. In their exploration, Al-Aidaros, Shamsudin & Idris critique Western ethical theories and advocate for Islam's holistic understanding of ethics. They stress the importance of nuanced approaches that honor diverse belief systems in the context of medical research [16].

Hassan discussed Islamic-based research methodology for development studies, defining it as a combination of theology and Islamic teachings. The paper aimed to identify and analyze the use of Islamic-based research methodology for development studies. Utilizing documentary research and content analysis, it identified various Islamic studies applicable to research design, data collection, and analysis methods for development studies [17]. Abu Bakar et al. explored the importance of Islamization in contemporary Islamic research, aiming to examine its application through various models offered by scholars. Findings revealed strengths and weaknesses in each paradigm and suggested that Western research procedures could support contemporary Islamic research to enhance quality. The study contributes to understanding Islamization in contemporary Islamic research methodology [18].

Wan Khairuldin explored the need for Islamic-based research methodology due to shortcomings in conventional methods and differences in Islamic philosophy and epistemology. The study aimed to identify current Islamic research methodologies and evaluate their applicability. Content analysis revealed an urgent need for Islamic research methodologies tailored to Islamic contexts, signaling a starting point for comprehensive development [19].

The literature review underscores the evolution of ethical standards in health research through an Islamic lens, acknowledging the unique considerations and principles within Islamic ethics. It examines how historical milestones such as the Nuremberg Code and the Declaration of Helsinki align with Islamic principles of justice, beneficence, and respect for human dignity. Furthermore, it explores how Islamic teachings emphasize the importance of preserving life, promoting well-being, and ensuring equity in healthcare research. Through content analysis, the review identifies the intersection of Islamic ethics with contemporary ethical dilemmas in health research, including issues of informed consent, protection of vulnerable populations, and ethical oversight. It considers how Islamic scholars and institutions

approach ethical deliberations in epidemiologic studies, clinical trials, and public health interventions, emphasizing the compatibility between Islamic values and modern ethical frameworks.

Moreover, the review highlights the role of Islamic jurisprudence (fiqh) and ethical guidelines derived from the Qur'an and Hadith in guiding research practices. It discusses the importance of incorporating Islamic principles into Institutional Ethical Review Boards (IERBs) and Research Ethics Committees (RECs) to ensure that research aligns with Islamic values and principles. Thus, it is imperative to conclude that, the review emphasizes the relevance of Islamic ethics in shaping the discourse on ethical standards in health research. It underscores the need for researchers and institutions to engage with Islamic teachings and ethical guidelines to foster ethical conduct and ensure the integrity of health research within Islamic contexts.

## **METHOD**

The methodology for the article "The Evolution of Ethical Standards in Health Research: An Islamic Overview" entails a multifaceted approach aimed at comprehensively analyzing the historical trajectory of ethical standards within health research, particularly through the lens of Islamic perspectives. Through an extensive literature review, key milestones in the development of ethical frameworks, including seminal documents on the Nuremberg Code and the Declaration of Helsinki, are identified and examined. Content analysis techniques are then applied to primary sources and secondary literature to uncover recurring themes and shifts in ethical paradigms, while also integrating Islamic ethical principles such as justice, beneficence, and autonomy. A comparative analysis between Western and Islamic ethical frameworks is conducted to explore points of convergence and divergence, enriched by case studies and consultation with the works of experts in bioethics and Islamic studies. This rigorous methodology ensures a comprehensive exploration of ethical standards in health research, fostering a nuanced understanding of the interplay between Western and Islamic perspectives on bioethics.

## **RESULTS AND DISCUSSION**

### **Early Historical Periods**

The origins of research ethics can be traced back to horrifying incidents during the Third Reich, where Nazi doctors conducted inhumane experiments on concentration camp prisoners, including killing twins to study eye color differences and forcing prisoners of war to drink seawater. Similar unethical experiments occurred globally, such as a South African oncologist administering excessive chemotherapy without consent, New Zealand women with cervical cancer denied standard treatment, and US prisoners subjected to dangerous studies. These incidents underline the necessity of ethical guidelines in research. In a recent South African trial, researchers even used a placebo control instead of the best-proven therapeutic method, highlighting ongoing ethical challenges in research. The foundation of research ethics, therefore, can be traced back to troubling historical incidents, such as the experiments conducted by the Nazis and unethical trials that took place globally. These cases highlight the vital significance of ethical guidelines in safeguarding the well-being of research participants and maintaining ethical standards in research procedures.

The ethical and professional standards within epidemiology and public health have been delineated through guidelines developed by various organizations. These guidelines encompass responsibilities to research participants, society, employers, and colleagues, shedding light on obligations concerning environmental hazards and impacted communities. For instance, ethics guidelines by the Industrial Epidemiology Forum, the International Society for Environmental Epidemiology, and the American

College of Epidemiology outline essential duties, values, and virtues in epidemiology. They emphasize the need for risk minimization, participant welfare protection, equitable distribution of benefits and risks, confidentiality, informed consent, ethical review, conflict resolution, and community obligations.

The genesis of international ethical standards in medical research traces back to pivotal historical events. Following the atrocities committed during World War II, the Nuremberg Code (1947) established ten principles emphasizing voluntary consent for research involving human subjects. The Universal Declaration of Human Rights (1948) reiterated the prohibition of cruel treatment and explicitly outlined the need for consent in medical experimentation. Subsequent human rights instruments, including protections for women and children, reinforced the ethical principles underpinning international research guidelines. Notably, the World Medical Association's Declaration of Helsinki (1964), evolving over time and most recently revised in 2008, is a fundamental international document shaping research ethics. Furthermore, various international organizations have issued ethical guidance on clinical trials, including directives from the World Health Organization (WHO), the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), the Joint United Nations Programme on HIV/AIDS, the Council of Ministers of the European Union, and the Council of Europe. These regulations and protocols aim to ensure ethical standards in biomedical research and clinical trials, echoing the evolving landscape of ethical practices in research involving human participants.

Mohamed, Shitindo, & Gasch contend that the Nuremberg Code emphasized the importance of informed voluntary consent, the freedom to withdraw from research, protection from physical and mental harm, and a careful consideration of the risk-benefit balance. The Helsinki Declaration of 1964 underscored the necessity of non-therapeutic research and prioritized the protection of subjects by emphasizing that individual well-being takes precedence over scientific or societal needs. While more declarations on research ethics emerged, these guidelines primarily targeted physicians and did not directly address research in developing countries.

The Council for International Organization of Medical Sciences (CIOMS) eventually tackled these issues in collaboration with the World Health Organization (WHO) and proposed guidelines for international research. These guidelines were later amended in 1993 and are currently undergoing further revisions. While these guidelines are not legally binding on nation-states, they hold moral authority and significantly influence research policy, particularly in the developing world. Africa, in particular, has not been exempt from instances of unethical research, with numerous reports documenting such abuses, including unethical experimentation and clinical trials. For example, in the 1990s, studies were conducted on 500 patients in Zimbabwe, the majority of whom were indigenous Africans, using new drugs and anesthesia without approval from the National Drugs Authority and without the patients' knowledge, resulting in up to six deaths. Another study testing the efficacy of breast cancer chemotherapy on South African women was conducted without research ethics approval or individual informed consent.

Hoeyer, Dahlager & Lynøe argue that there has been a significant shift in the medical ethos due to the increased emphasis on protection. Initially, the primary goal was to do good (beneficence), but the introduction of research introduced a need to balance the interests of various stakeholders, including current and future patients, researchers, and research subjects. The Tuskegee syphilis study in 1972 and the subsequent Belmont report highlighted the importance of non-maleficence, emphasizing the principle of doing no harm. This shift has sometimes been seen as a hindrance to research, leading to complex and occasionally questionable rules regarding informed consent and approval procedures. However, most medical

researchers are committed to safeguarding the rights of research participants, with informed consent being a central aspect of these efforts, even in cases where the initial concern may not directly relate to assessing risks to an individual's body, such as in biobank based research.

Throughout history, human interaction, including research involving people, inherently carries ethical considerations. Yet, ethical conduct encompasses more than mere adherence to rules; it involves a deeper respect and care for others. This National Statement on ethical conduct in human research emphasizes a fundamental ethos guiding how research is approached, extending beyond ethical guidelines to shape researchers' overall approach to their work. While much human research contributes positively and safely to society, there are instances where risks and ethical issues arise, whether due to oversight, technical errors, or, in extreme cases, deliberate ethical violations, notably exemplified by World War II experiments. The involvement of individuals in research raises crucial ethical questions, particularly regarding trust between participants and researchers and the altruistic contribution of participants for the greater good. Ethical reflections on medical research trace back to ancient times, gaining momentum after World War II, highlighted by the Nuremberg Code and subsequent international human rights instruments. This period also saw the development of comprehensive ethical guidelines, such as the Helsinki Declaration, acknowledging the need for ethical conduct in research practices across diverse fields.

The expanded scope and authority of the National Statement on research ethics underscore the critical need for comprehensive guidelines that balance flexibility with participant protection. Rooted in the lessons from tragic instances like the Tuskegee syphilis study, these guidelines prioritize the principles of non-maleficence and "do no harm." While they might pose challenges to research endeavors, these principles serve as crucial safeguards, ensuring the rights and safety of individuals involved in studies. The National Statement stands as a testament to the imperative of ethical considerations in evolving research landscapes, striving to prevent past injustices and mitigate potential harm in future investigations.

### **The Nuremberg Code**

The Nuremberg Code encompasses key principles such as informed consent and the absence of coercion, scientifically sound experimentation, and a commitment to the well-being of research participants. This code stipulates the following principles: 1) Voluntary informed consent is indispensable and must not involve any form of pressure or coercion; 2) Human experiments should be grounded in prior animal testing; 3) Anticipated scientific benefits should justify the experiments; 4) Only qualified scientists should conduct the experiments; 5) Experiments should be carried out in a way that avoids unnecessary physical and mental suffering and harm; 6) There should be no expectation of death or disabling injury resulting from the experiment. The Code stands as a timeless and ethical framework that evaluate the fundamental principles of research ethics, emphasizing the paramount importance of informed consent, scientific rigor, and the safeguarding of human dignity in all research involving human subjects. These principles continue to guide and inform ethical research practices today, serving as a poignant reminder of the moral imperative to prioritize the welfare and autonomy of individuals participating in scientific experiments.

A consent form is a comprehensible written document that records a potential participant's agreement to participate in research and outlines the rights of a research participant. This document should clearly and respectfully communicate the following information: the research's time-frame; research title; researchers involved; research purpose; a description of the research; potential risks and benefits;

alternative treatments; confidentiality assurances; details on information and data collection, storage, and access; disclosure of any conflicts of interest; a statement affirming the participant's right to withdraw from the study at any point; and a declaration that the potential participant understands and agrees to these terms. The consent form should be in a language the potential participant understands, and for individuals with limited literacy, verbal communication of the consent details should be provided, along with appropriate documentation if consent is given.

In public health research, informed consent is crucial for participants, ensuring they freely agree and legally permit their involvement. It involves divulging all details—research aims, methods, risks, benefits, and the option to withdraw. Yet, there are exceptions: consent might not be needed if impractical, risks are low, and a review committee weighs everything. Some studies, like certain epidemiology ones using vast databases, might skip re-contacting patients due to practical reasons. Dealing with disadvantaged groups needs extra care—misunderstandings about accessing healthcare, feeling pressured by authority, or being motivated by money can arise. Ethical dilemmas also surface in international research involving language barriers or developed country researchers in developing nations.

A well-constructed consent form in research plays a critical role by documenting a participant's agreement while safeguarding their rights. It must encompass key elements such as research specifics, potential risks, benefits, confidentiality, and withdrawal rights. In addition, it's vital to ensure clear communication, especially in a language the participant comprehends, and offer verbal explanations for those with limited literacy. In sum, this underscores the ethical and legal significance of informed consent, ensuring transparency and respect for research participants.

### **The Declaration of Helsinki**

In 1953, the World Medical Association (WMA) was prompted to create drafts that would apply the principles of the Nuremberg Code to human experimentation within the medical community. This resulted in the Declaration of Helsinki, which expanded upon the Nuremberg Code and was first adopted in 1964. Subsequent revisions were made in 1975, 1983, 1989, 1996, 2000, and most recently in 2008 to align with contemporary ethical theory and evolving clinical and research practices. A significant departure from the Nuremberg Code was the Declaration's allowance for flexibility in consent conditions, as opposed to the Nuremberg Code's requirement of 'absolutely essential' consent. The Declaration of Helsinki permitted research without direct consent when proxy consent, such as that from a legal guardian, was available. This declaration introduced the concept of an independent committee, which later evolved into the institutional review board (IRB) system employed in the United States. Notably, the Declaration's flexibility in consent conditions marked a departure from the Nuremberg Code, reflecting a more nuanced understanding of ethical research consent. Through subsequent revisions, the Declaration has adapted to contemporary ethical theory and changing clinical and research practices.

The Declaration of Helsinki emphasizes a systematic approach, including IRB review, in contrast to the Nuremberg code, which centered on the individual scientist's responsibility, lacked legal enforcement, and applied only to non-therapeutic clinical research. The Declaration of Helsinki holds significant historical importance in research ethics as the medical community's initial substantial effort to regulate research practices itself. It serves as the foundation for subsequent ethical guidelines and is widely acknowledged as the fundamental document in the field of human research ethics. Its historical significance lies in being the medical community's first substantial effort to regulate its research practices, shaping ethical standards for the protection of research participants and the integrity of scientific inquiry. The

Declaration of Helsinki remains a cornerstone document, continuing to guide and inspire ethical research endeavors worldwide.

Regarding the Declaration of Helsinki, when a country's Minister decides that South African research must adhere to this document, it becomes a potent tool as violating its principles would mean a violation of Department of Health regulations. However, this can be challenging because the Declaration undergoes frequent revisions, and the Minister has no say in its content. If the Minister mandates adherence to the Declaration, she must hope that it remains acceptable, or else South African regulations would need adjustment. In the module on 'Other Issues,' it will become apparent that some ethical documents lack legal authority, but compliance with their guidelines is crucial if researchers wish to have their work published in respected journals. Ethical guidelines on authorship, for instance, dictate specific procedures, and failure to follow them can result in leading journals in the field refusing to publish the work.

The Declaration of Helsinki stands as a pivotal milestone in the history of research ethics. Born out of the need to address unethical human experimentation following the Nuremberg Trials, this declaration has evolved and expanded upon the principles of the Nuremberg Code. It introduced a systematic approach to ethical research practices, emphasizing the importance of independent oversight through institutional review boards (IRBs).

### **Institutional Review Boards (IRBs)**

The concept of Institutional Review Boards (IRBs) as we know them today originated in the 1970s. It is now mandatory for all proposals involving human participants in biomedical research to undergo review and approval by an appropriately constituted institutional ethical review board, which may also be referred to as an institutional ethics committee (IEC), ethics review board (ERB), or Research Ethics Board (REB) in different countries. Two fundamental characteristics of these boards are competence and independence. The responsibilities of an IRB include safeguarding the dignity, rights, and well-being of potential research participants, ensuring that universal ethical principles and international scientific standards are adapted to local values and customs, and assisting in the development and education of a research community that is responsive to local healthcare needs. These boards are responsible for reviewing research proposals before the projects commence and also for monitoring approved research projects to ensure ongoing compliance with ethical standards. The actions taken by an IRB can include approval without conditions, approval with conditions, rejection of a proposal, or the termination of an ongoing investigation in cases of noncompliance.

The purpose of Institutional Review Boards (IRBs) or Research Ethics Committees (RECs) is to ensure that research involving human participants upholds ethical standards and safeguards participants' rights and well-being. They assess the balance of risks and benefits, equitable participant selection, and the adequacy of informed consent procedures. These committees aim to prevent unethical research, primarily by conducting ethical reviews and providing opinions on research proposals. The historical context, such as the Tuskegee study, led to the development of bio-ethical principles and the establishment of IRBs to oversee research ethics. Approaches to research ethics include emphasizing valid consent (autonomy), ensuring participant safety (duty of care), and weighing foreseeable consequences (consequentialism) [20].

For research proposals involving human participants, a scientific evaluation by an appropriate Scientific Review Committee typically precedes the ethical review process. The IRB secretariat reviews the research proposal for completeness and,

based on the level of risk involved, categorizes it into three types: exemption from review, expedited review, and full review. Proposals with less than minimal risk may qualify for exemption from review and can be administratively reviewed without the need for full board review. Proposals presenting no more than minimal risk to participants may undergo expedited review, usually by a sub-committee. Research involving more than minimal risk, those that don't qualify for exemption or expedited review, and studies involving vulnerable populations or special groups are subject to full review by all members of the IRB. Research intended for publication is typically reviewed by the institutional review board.

It is crucial to recognize that the ethical guidelines and principles discussed are not just historical relics but continue to shape contemporary research practices. The efforts to protect the rights of research participants and uphold the values of informed voluntary consent, freedom to withdraw from research, and the careful consideration of risk-benefit balances remain central in the ethical conduct of research.

### **Bioethics Movement**

Bioethics is an area of ethical inquiry that examines ethical dilemmas and issues arising from healthcare, health-related practices, and research involving humans. In a broader historical context, scholars have recently made significant progress in connecting the emergence of the bioethics movement to the secularization of society in liberal democracies during the late 20th century. Bioethics provided an attractive alternative for governments in increasingly pluralistic societies as traditional sources of authority, such as religious traditions, waned. Bioethics offered a set of 'thin' moral principles (autonomy, beneficence, justice) that could easily be translated into liberal policies and regulations focused on patient rights. Thus, bioethics thrived because it met the needs of the bureaucratic state in a secularizing political climate, providing a way to reason about complex moral and technical questions. Research Ethics Committees (RECs) can be seen as a method for "reasoning together" about medicine and science, placing democratic constraints on medical research while legitimizing its conduct [21].

The bioethics movement has emerged as a crucial framework for navigating the intricate terrain of healthcare, medical practices, and research involving humans. Its historical roots, intertwined with the changing dynamics of society, reflect the need for a secular and adaptable ethical foundation in our increasingly diverse and complex world. By prioritizing values such as autonomy, beneficence, and justice, bioethics has not only influenced policies and regulations but also served as a means for democratic deliberation on matters of medicine and science.

The ethical principles established in various instruments and guidelines governing biomedical research are designed to safeguard the dignity, rights, safety, and wellbeing of research participants. The independent evaluation of the scientific merit of a research project and an ethical review are central to upholding these principles. The enduring relevance of bioethics lies in its unwavering commitment to safeguarding the dignity, rights, safety, and well-being of those who participate in biomedical research. The ethical principles embedded in institutional guidelines ensure that the pursuit of knowledge and advancements in healthcare remain grounded in respect and responsibility.

### **Contemporary Ethical Guidelines**

The National Research Act of 1974 represents a pivotal moment in the history of ethical guidelines for human research, triggered by the profound moral lessons learned from the Tuskegee Syphilis Study. This landmark legislation gave birth to the National Commission for the Protection of Human Subjects of Biomedical and

Behavioral Research, demonstrating a commitment to preventing such egregious violations of human dignity and rights in the future. The commission's noble mission was to define the core ethical principles that should underpin all research involving human participants. Their dedication resulted in the creation of the Belmont Report in 1979, a seminal document that continues to serve as the bedrock for ethical conduct in human research within the United States.

Therefore, contemporary ethical guidelines in human research find their roots in the aftermath of the Tuskegee Syphilis Study and the subsequent enactment of the National Research Act in 1974. The establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research reflects a commitment to preventing ethical violations, leading to the development of the Belmont Report in 1979. This influential document continues to be a cornerstone for ethical standards in human research within the United States, emphasizing the enduring importance of safeguarding human dignity and rights in the field of research.

### **The Belmont Report**

As part of its mandate, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research produced the Belmont Report in 1979. This report aimed to summarize the core ethical principles identified by the commission during its deliberations. The Belmont Report provides a framework of fundamental ethical principles and guidelines to help address the ethical challenges surrounding research involving human participants [22]. It played a crucial role in shaping the U.S. Department of Health and Human Services (HHS) Code of Federal Regulations (45 CFR 46), which was established in 1974 and later revised. In 1991, Subpart A of these regulations, known as the "Basic HHS Policy for the Protection of Human Research Subjects," was adopted by 15 federal agencies and became known as the Common Rule. In 2017, HHS and 15 other federal agencies issued a revised version of 45 CFR 46, Subpart A, aimed at strengthening human subject protections and improving research administration and operations. Twenty agencies, including HHS, intend to follow this revised common rule [23].

The enduring legacy of the National Research Act and the Belmont Report is a testament to the commitment of safeguarding the well-being and autonomy of individuals involved in research. These guidelines serve as a constant reminder of the responsibility we bear to ensure that the pursuit of knowledge never comes at the expense of human dignity and rights.

### **Global Harmonization**

Understanding what constitutes ethical research is crucial for all researchers and individuals who engage with research outcomes. Researchers should possess a solid grasp of fundamental ethical principles and stay updated on policies and procedures aimed at safeguarding research participants and ensuring the integrity of research. Ignorance of these policies cannot excuse ethically questionable projects. Thus, it is the responsibility of researchers to proactively seek and comprehend the policies and theories that promote ethical research practices. Research is a public trust that demands ethical conduct, trustworthiness, and social responsibility for its findings to be valuable. Every aspect of a research project, from its design to the submission of results for peer review, must adhere to ethical standards. When even one aspect of a research project is dubious or unethical, it can cast doubt on the entire project's integrity. Ethical research is the cornerstone of trust in the scientific community. Researchers must be well-versed in ethical principles, stay updated on relevant policies, and actively seek to promote ethical research practices. Any lapse in ethical standards, even in one aspect of a research project, can jeopardize its entire credibility.

Given the crucial role of ethics in research, it is not surprising that numerous professional associations, government agencies, and universities have established specific codes, regulations, and policies related to research ethics. Many government agencies, including the National Institutes of Health (NIH), the National Science Foundation (NSF), the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the US Department of Agriculture (USDA), have ethics rules governing funded research. Other influential research ethics policies include the Singapore Statement on Research Integrity, the American Chemical Society's Code of Ethics, the American Psychological Association's Ethical Principles of Psychologists and Code of Conduct, and the Nuremberg Code and the World Medical Association's Declaration of Helsinki, among others [24].

Certainly, a global harmonization of ethical standards in research is imperative. Researchers bear the responsibility of upholding ethical principles, staying informed about policies, and ensuring the integrity of their work. With numerous organizations and international guidelines in place, the commitment to ethical research practices remains vital for the credibility and trustworthiness of the entire research community.

### **The Islamic-Based Research Methodology**

The Islamic-based research methodology emphasizes the Islamic tradition of seeking knowledge, pondering, and conducting research. Rooted in Islamic law and principles, this methodology aims to uncover essential truths and propose solutions to contemporary issues, particularly in the social sciences. Despite the prevalence of Western research methods, some Islamic scholars advocate for the Islamization of research to align with Islamic epistemology and philosophy.

Defined as a research method integrating theology, reasoning, narration, and observed knowledge, Islamic-based research places Islamic principles at its core. This approach has gained prominence, exploring various aspects of life from an Islamic perspective, including economy, social issues, and management. The surge in Islamic-based research is attributed to historical events like the Iranian revolution, the 2001 World Trade Centre bombing, and the Arab Spring. While Islam historically encouraged research during the golden ages, the decline in research culture occurred after the fall of Muslim leadership in Baghdad and Spain. However, the Qur'an contains explicit instructions urging Muslims to engage in research, encouraging the study of historical facts and the use of common sense and experimentation.

The Islamic research methodology challenges the positivist paradigm's emphasis on empirical evidence, highlighting the Qur'an's focus on the spiritual faculty known as *al-fu'ad*. The Qur'an motivates the study of both physical and social phenomena, guiding believers to recognize the truth in various regions of the earth and within themselves. This encouragement is evident in verses emphasizing signs on earth and within souls. In contemporary times, research in Islam extends beyond traditional subjects to explore Islam's influence on education, religion, politics, and economics. Many universities in Muslim-majority areas include the study of Islam as part of modern scholarship, promoting a comprehensive understanding of Islamic knowledge [25].

Al-Qur'an inspires human beings to study both physical and social phenomena. Allah said in the Qur'an,

We will show them Our signs In the universe, and in their own selves, until it becomes manifest to them that This (the Qur'an) is the truth. is it not Sufficient In regard to Your Lord that He is a witness over All things.

The Qur'an motivates the study of both physical and social phenomena, urging humanity to recognize the truth in various regions of the earth and within themselves.

"Afaq" pertains to physical sciences, while "anfus/nafs" relates to social sciences. This encouragement is reiterated in verses emphasizing signs on earth and within souls. Same encouragement can equally be found in many Qur'anic verses, where Almighty Allah Says:

On the earth are signs for those of assured faith. As also in your own souls/selves, will you not then see?

Islamic ethics serve as a guiding light for researchers, emphasizing sincerity, integrity, and adherence to Islamic principles throughout the research process. With a foundation rooted in Qur'anic teachings, Islamic research ethics stress the importance of transparency, honesty, and respect for human dignity. As Islamic bioethics and research methodologies continue to evolve in order to uphold the sanctity of human life and prioritize ethical conduct in all endeavors.

### **Morals and Ethics in Research: The Islamic Perspectives**

Ethics in Islam are rooted in good principles and values derived from Islamic sources, guiding human behavior across all aspects of life. In Islam, ethical conduct is closely tied to faith (Iman), wherein strong faith correlates with virtuous character. The Prophet Muhammad (peace be upon him) emphasized the connection between faith and ethics, highlighting the importance of treating others with kindness and avoiding harm through words and actions.

Islamic ethics extend to various domains, including research, where researchers are encouraged to conduct their work with sincerity and integrity, aligning their intentions with the teachings of Islam. Upholding ethical standards in research involves respecting respondents, ensuring confidentiality, and maintaining honesty throughout the research process. Islamic researchers are advised to prioritize the purpose of research for the sake of Allah (SWT) and adhere to transparent and unbiased practices.

While Islam provides general ethical guidelines, specific codes of ethics for Islamic research are still developing. Some Western research ethics codes may be adopted as long as they align with Islamic principles. The teaching of Islam encompasses all areas of human activity, with Shari'ah serving as the guiding legal framework. Shari'ah sources, including the Qur'an, Sunnah, consensus, analogy, and secondary sources, provide flexibility to adapt to different contexts while upholding core principles such as protecting religion, life, lineage, health, and property.

In dealing with ethical dilemmas, Islam emphasizes prioritizing benefits while minimizing harm, ensuring that actions align with overarching ethical goals. This comprehensive ethical framework reveals Islam's relevance in navigating contemporary challenges, including those encountered in research and medical practice.

Islam offers a comprehensive framework of overarching principles applicable to address life's challenges. The initial principle assesses if an action aligns with fundamental laws' underlying principles. These encompass safeguarding religion, preserving life, honoring ancestry, maintaining mental and physical well-being, and protecting property. The subsequent principle ensures that potential drawbacks don't compromise the fulfillment of benefits or interests.

In Islam, the sanctity of human life is paramount, and ethical principles derived from Qur'anic teachings shape health research practices. Qur'anic verses provide guidance on confidentiality, justice, and the preservation of life, informing ethical decision-making in healthcare and research. Islamic law offers a comprehensive moral framework, ensuring that ethical considerations are integral to medical practices and research endeavors.

## Islam, Ethics and Health Research

In Islam, human life is regarded as a precious gift from God, and its sanctity is emphasized through Qur'anic verses. The Qur'an promotes the preservation of life and condemns the unjustified taking of it. This perspective has driven interest in Islamic bioethics, focusing on the imperative to save lives and adhere to Islamic law and ethics. Islamic bioethics states that decisions and behaviors in health and research must align with Shari'ah (Islamic law) and ethical principles. Allah says in the Glorious Qur'an:

Because of that we ordained for the Children of Israel that if anyone killed a person not in retaliation of murder, or (and) to spread mischief in the land - it would be as if He killed All mankind, and if anyone saved a life, it would be as if He saved the life of All mankind. and indeed, there came to them Our Messengers with clear proofs, evidences, and signs, even Then after that many of them continued to exceed the limits (e.g. by doing oppression unjustly and exceeding beyond the limits set by Allah by committing the major sins) In the land!.

Research ethics in Islam is guided by Qur'anic verses that emphasize broad principles such as confidentiality, non-maleficence, and justice. Verses highlight the importance of avoiding harm, maintaining justice, and standing firmly for fair dealing. Islam encourages believers to act justly in all aspects of life, including research, and to uphold moral and ethical principles as part of their faith [26]. There are many verses on the broad guidelines for research ethics as relate to confidentiality, non-maleficence, justice, and others. The following are among them;

He (the father) said: "O My son! relate not Your vision to Your brothers, lest they arrange a plot against you. Verily! Shaitan (Satan) is to man an open enemy!.

Verily! Allah commands that You should render back the trusts to those, to whom they are due; and that when You judge between men, You judge with justice. Verily, how excellent is the teaching which He (Allah) gives You! Truly, Allah is ever All-Hearer, All-Seer.

O You who believe! stand out firmly for justice, as witnesses to Allah, even though it be against yourselves, or Your parents, or Your kin, be He rich or poor, Allah is a better protector to both (than you). so follow not the lusts (of Your hearts), lest You may avoid justice, and if You distort Your witness or refuse to give it, Verily, Allah is ever Well-Acquainted with what You do.

O You who believe! stand out firmly for Allah and be just witnesses and let not the enmity and Hatred of others make You avoid justice. be just: that is nearer to piety, and fear Allah. Verily, Allah is Well-Acquainted with what You do.

Say (O Muhammad): My Lord has commanded justice and (said) that You should face Him Only (i.e. Worship none but Allah and face the Qiblah, i.e. the Ka'bah at Makkah during prayers) In each and Every place of worship, in prayers (and not to face other false deities and idols), and invoke Him Only making Your Religion sincere to Him by not joining in Worship any partner to Him and with the intention that You are doing Your deeds for Allah's sake only. as He brought You (into being) In the beginning, so shall You be brought into being (on the Day of Resurrection) [in two groups, one as a blessed one (believers), and the other as a wretched one (disbelievers)].

Verily, Allah enjoins Al-Adl (i.e. justice and worshipping none but Allah alone - Islamic Monotheism) and Al-Ihsan [i.e. to be patient In performing Your duties to Allah, totally for Allah's sake and In accordance with the Sunnah (legal ways) of the Prophet In a perfect manner], and giving (help) to kith and kin (i.e. All that Allah has ordered You to give them e.g., wealth, visiting, looking after them, or any other kind

of help, etc.): and forbids Al-Fahsha' (i.e. All evil deeds, e.g. illegal sexual acts, disobedience of parents, polytheism, to tell lies, to give false witness, to kill a life without right, etc.), and Al-Munkar (i.e. All that is prohibited by Islamic law: polytheism of Every kind, disbelief and Every kind of evil deeds, etc.), and Al-Baghy (i.e. All kinds of oppression), He admonishes you, that You may take heed.

Islamic law, encompassing a comprehensive system of morality, inherently provides a moral context in medicine. The flexibility of Muslim teachings allows adaptation to new situations, and ethical guidelines are seen as integral to Islamic law. In Islam, ethical teachings are not a separate discipline but are integrated into the legal framework, with morality and ethics considered absolute and of divine origin. The fixed moral and legal principles within Islam are deemed broad enough to address the ethical needs of all times and places [27].

Moreover, the "Islamic code of medical and health ethics" established by the Regional Committee for the Eastern Mediterranean further emphasizes core principles rooted in Islamic values. These include the recognition of human dignity, the sanctity of life, equity in healthcare, excellence in care, and the obligation to avoid harm. The code reinforces the ethical obligation to provide high-quality healthcare, respecting individual rights and ensuring equal access to healthcare for all, without discrimination based on gender, race, or belief. This code reflects the enduring traditions within Islamic culture and serves as a guide for ethical medical practices [28].

The Islamic code of medical and health ethics, endorsed by the Regional Committee for the Eastern Mediterranean, reflects the core values of Islamic principles. It underscores the importance of human dignity, equity in healthcare, and the obligation to provide compassionate and high-quality care. Rooted in Islamic culture and tradition, this code serves as a beacon for ethical medical practices, promoting equal access to healthcare and prioritizing patient well-being.

### **Impacts of Ethical Violations**

In a tragic incident in 1996, Pfizer conducted tests of Trovan, an experimental drug, on nearly 200 children during a meningitis outbreak. Children in the control group allegedly received an inadequate dose of Ceftriaxone, and eleven died, while some survivors suffered permanent brain damage and paralysis. It later emerged that the clinical trial had not been approved by a local research ethics committee, and the affected families were not adequately informed that their children were research participants. This highlights the critical importance of learning from past mistakes. Similarly, in 2001 in Nigeria, Pfizer faced a lawsuit from 30 families over trials of the Trovan antibiotic intended to treat meningitis.

Globally, ethics guidelines for research involving human subjects have often drawn from practices developed primarily for medical research. Research Ethics Committees (RECs) play a vital role in preventing sex- and gender-blind research that neglects the impact of sex and gender differences on individual and population health. Adhering to universally accepted biomedical research ethics principles, such as respect for autonomy, non-maleficence, beneficence, and justice, indicates the significance of promoting research that takes sex and gender into account.

The tragic incident involving Pfizer's unethical testing of Trovan on children in 1996 serves as a sobering reminder of the severe consequences of ethical violations in research. The loss of innocent lives and the enduring suffering of survivors underscore the paramount importance of ethical research practices. This case also emphasizes the need for stringent oversight and adherence to ethical guidelines, especially in medical research. This tragic consequences of ethical violations in research, as exemplified by the Pfizer incident, underline the irreplaceable value of

ethical conduct in all research endeavors. Researchers must continue to learn from past mistakes, uphold the highest ethical standards, and ensure that research respects the dignity and well-being of all individuals. By doing so, we can foster trust in research, advance scientific knowledge, and promote the betterment of society as a whole.

## CONCLUSION

In conclusion, the trajectory of research ethics throughout history has witnessed profound revelations and transformative changes in medical principles. From the dark episodes of the Nazi regime to the formulation of ethical frameworks like the Nuremberg Code and the Helsinki Declaration, the emphasis on safeguarding the rights and welfare of research participants has become imperative. These ethical standards, largely shaped by medical research paradigms, highlight the important role of Research Ethics Committees (RECs) in addressing gender and sex distinctions in research. Aligned with the core tenets of biomedical research ethics, RECs uphold principles of autonomy, prevention of harm, promotion of benefits, and ensuring fairness, advocating for research that acknowledges the rights of participants of the research. Furthermore, ethical guidelines emphasize values such as honesty, objectivity, integrity, transparency, and the protection of human subjects, encompassing broader considerations including legality, animal welfare, competence, and societal accountability. Introducing an Islamic perspective into this discourse could further enrich discussions on research ethics, integrating principles from Islamic literature to provide a more holistic approach to ethical deliberations in research practices.

## Recommendations

In light of these discussions, several recommendations emerge to advance ethical research practices:

1. Strengthen REC Engagement: Enable RECs to champion and supervise research that is sensitive to various participant characteristics, extending beyond solely gender or sex considerations.
2. Interdisciplinary Cooperation: Cultivate partnerships among researchers, ethicists, and policymakers to incorporate emerging ethical norms into a wide array of research disciplines.
3. Ethical Education: Advocate for comprehensive ethics education for researchers, stressing the significance of recognizing and addressing diverse participant characteristics, including sex and gender.
4. Continuous Evaluation: Promote regular assessment and adaptation of ethical guidelines to address emerging ethical dilemmas.
5. Public Education: Increase public awareness regarding the significance of ethical research practices and the pivotal role of RECs in safeguarding the rights of research participants.

By embracing these recommendations, the field of research ethics can continue to evolve and uphold the highest standards of ethical conduct, fostering a culture of responsibility and trustworthiness within the global research community.

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