The Research of Medical Science Review
ISSN: 3007-1208 & 3007-1216 Volume 3, Issue 12, 2025

INTERNATIONAL LEGAL FRAMEWORK FOR THE REGULATION OF BIOMEDICAL RESEARCH AND GENETIC DATA SHARING

Muhammad Zeeshan[*1], Dr. Tansif Ur Rehman[2], Dr. Aisha[3]

[*1]*Department of Law, Dadabhoy Institute of Higher Education, Pakistan*
[2]*Tansif Ur Rehman, Teaching Associate, Department of Sociology, University of Karachi, Pakistan; and Visiting Faculty, Department of Law, Dadabhoy Institute of Higher Education, Pakistan*
[3]*Women Medical Officer, Civil Hospital Naushahro Feroze*

[*1]malakshan162@gmai.com, [2]tansif@live.com, [3]aishasolangi786@gmail.com
[2]https://orcid.org/0000-0002-5454-2150

DOI: https://doi.org/10.5281/zenodo.20698466

Keywords
challenges, historical context, laws, opportunities, theoretical context

Article History
Received: 13 October 2025
Accepted: 25 November 2025
Published: 10 December 2025

Corresponding Author: *
Muhammad Zeeshan

Abstract
The rapid expansion of biomedical research and the additional use of genetic information have created complex global ethical, legal and regulatory challenges. The age of collaborative research, with data crossing countries in increasing numbers, has never been in greater need of a workable international legal framework. The paper will discuss the evolution of the law in regard to medical research and the use of genetic information, the rights of the participants, information privacy, informed consent and the broader ethical considerations. It also produces anomalies in national law and regulatory gaps, which are huge impediments to efficient and safe data transfers, especially in the new economies. The article underscores one of the ways for the protection of human dignity and development of science, namely transparency, accountability and harmonized legal standards. It also means international cooperation and capacity building for ethical biomedical practice in the context of new technologies. The paper ends with recommendations for a flexible legal policy.

INTRODUCTION

The pace of progress in genetic technologies and biomedical research is now staggeringly high, and it can result in far-reaching changes in the healthcare system and provide unprecedented opportunities to diagnose, prevent and treat diseases more effectively (Federico & Trotsyuk, 2024). But the ethical and legal issues of science findings are sensitive and have some issues. One of them is transnational research, when there is a lot of genetic information that is shared across borders (Gao et al., 2024). The increasing internationalization of biomedical research has made it more difficult to provide consistent and meaningful protection of individual rights, privacy and informed consent (Blegen et al., 2024).

It is possible to add that the necessity to create the international law system, in its turn, is also logical, and the absence of such laws in the countries will probably complicate the cooperation and compatibility of the data, as well as the safety of the objects of the study (Mayo et al., 2023). Several global documents are trying to establish ethical and legal standards of biomedical research and management of genetic data (Casaletto et al., 2023). The World Medical Association in the Declaration of Helsinki, the UNESCO in the Universal Declaration on the Human Genome and Human Rights and the OECD in the

Guidelines on Human Biobanks and Genetic Research Databases introduce the informed consent principle, data privacy principle and ethical control principle. Despite these efforts, gaps in interpretation, enforcement and coverage remain, especially in low- and middle-income countries (Bak et al., 2023).

Research Justification

The explosive surge of genetic information and the sophistication of biomedical research have given rise to issues around data privacy, consent, data ownership, and data trans-border sharing. Technology such as Genome Sequencing, Biobanking and other technologies are being developed and applied more as the years go by, and an internationally harmonized legal framework is required to ensure ethical use alongside scientific innovation. Several countries have policies and legislations in place, and if there were any issues, problems or inconsistencies between countries, this would have a negative impact on human rights and undermine the collaboration.

Such study is substantiated by the fact that there is a great need to know more about the existing international legal mechanisms and the effectiveness of these mechanisms in regulating biomedical and genetic research. It attempts to find out the main areas where existing structures are not needed or not sufficient, especially in protecting the rights of the research participants and data protection. As more scientific research is undertaken around the globe, a thorough investigation should be undertaken that would assist in setting more unified, open and ethical policies. It will also contribute to the scientific and policy discourse by offering best practices, highlighting new ethical challenges and recommendations for legal convergence. The assessment of the international instruments and comparison of national practices will facilitate the development of future international norms in the field of biomedical research on genetic data.

Literature Review

The global ethical system of biomedicine research and the exchange of genetic information have been a major topic of scholarly discussion over the last few years (Brown et al., 2023). The principles of ethics in biomedical research are guided mainly by international declarations and standards such as the Declaration of Helsinki and the Belmont Report that introduce the principles of informed consent, minimize risks, and respect for the individual as a vital element (Akhtar & Gupta, 2024). But they are not legal frameworks adopted uniformly in many countries. Therefore, they are neither efficient nor effective (Casaletto et al., 2023).

The procedures may be useful in giving ethical guidance, but we must admit that there are no effective measures for enforcement. In particular, the security of genetic data that may have cross-border implications (Federico & Trotsyuk, 2024). The European Union General Data Protection Regulation (GDPR) is one of the most elaborate legislative systems for personal data and genetic information. It is based on a high consent, data security and privacy standard. (McKibbin & Shabani, 2023). However, the extraterritorial application outside the EU is rather limited and often not compatible with the local legislation of other countries, especially in situations of lesser data protection regulation. The collapse has been demonstrated to obstruct international cooperation and hinder multinational research (Bak et al., 2023).

Another major reason for the lack of infrastructure and technical skill is discussed in the recent literature as the difficulty of implementing and adopting strong regulatory systems in developing nations (van Gend & Zuiderwijk, 2023). Simultaneously, an increasing number of people are calling for a more integrated global system, with organizations such as the World Health Organization or UNESCO to coordinate legal and ethical activities (Mayo et al., 2023). The result has been a strong focus on fair data sharing, open data and the protection of vulnerable groups. This has been emphasized by different scholars and has been reflected in a general agreement in the urgent and binding processes of international law (Blegen et al., 2024).

Historical Context of the Regulation of Biomedical Research and Genetic Data Sharing

The abuses of science in the last century and the complexity of today's research have pushed for considerable progress in biomedical research and legislation on sharing genetic data (Gao et al., 2024). The world saw abuses of science under Nazi rule and developed the Nuremberg Code (1947). The Nuremberg Code, therefore, resulted in better policies concerning the justification of fully informed and voluntary patient consent. The Declaration of Helsinki was set up in 1964 and strengthened the World Medical Association to ensure full informed and voluntary patient consent (Blegen et al., 2024).

These policies reinforced current biomedical ethics and research law (van Gend & Zuiderwijk, 2023). Another step in the direction of upholding the laws and ethics of biomedical research internationally was the 1997 UNESCO Universal Declaration on the Human Genome and Human Rights (Federico & Trotsyuk, 2024). Genome drives and international biobanks have also put in place (2009) OECD Guidelines and CIOM (2002), and have and will continue to assist the protection framework for the ease and vulnerable (Akhtar & Gupta, 2024; Brown et al., 2023).

Theoretical Context of the Regulation of Biomedical Research and Genetic Data Sharing

The legal and moral philosophies that underpin the international legal approach to the governance of biomedical research and the sharing of genetic information are rooted in the principles of human dignity, autonomy and justice. The framework is adapted from the principles of bioethics, which have been used to assess risks, benefits, and ethical issues associated with human subject research. The most important pillars of the ethical argument and laws are: respect for persons, informed consent, beneficence, non-maleficence and justice.

Regulation of biomedical research by international bodies is also a significant part of the theory of human rights. It is based on the assumption that the rights of people to privacy, to their own bodies, and to be free from discrimination must not be violated when using their genetic properties for the purposes of science. Often these values are codified in law, policy or other policies, including access to personal information and to biological specimens. Principles of it in the public interest that attempt to strike a balance between the individual's rights and the good of the society in scientific development are regulatory systems. The blending of the theories is a normative model of formulation and application of international theories in modern biomedical and genetic research in today's world.

Laws Regarding the Regulation of Biomedical Research and Genetic Data Sharing

International legal framework for biomedical research and for the sharing of genetic resources is a developing framework of various soft laws, binding agreements, practices and ethical principles. It aims to ensure that research with human beings and involving genetic resources is carried out in an ethical, transparent and respectful manner. No international agreement to control this area. A lot of international instruments are establishing a regulatory framework.

The key elements of the legal framework are related to informed consent, privacy, data protection, cross-border data flows and benefit sharing. The declaration, such as the Universal Declaration on Bioethics and Human Rights, emphasizes an aspect of the importance of personal autonomy and rights to privacy in biomedical research. Likewise, the international standards demand that research subjects are provided with enough information about the nature, purpose, risks and benefits of being a research subject, particularly in genetic research.

However, there are rules regarding the sharing of data, too. The framework allows for open science, but also ensures the protection of sensitive information by anonymizing and/or coding the data to the degree that the participant(s) are not identifiable. Another aspect of the law placed emphasis on is the ethical approval of all biomedical research before it is conducted by independent committees. Such legal imperatives are aimed at balancing individual and collective rights with scientific progress.

Normally, these international instruments are supplemented by national legislation, with the problem of harmonization. Countries with inconsistent legal definitions, law enforcement and ethics standards experience a high rate of uncertainty in law. Hence, there is increasing pressure for making the laws uniform world over or the model laws can be customized at the national level so as to bring uniformity and predictability of law. The international jurisprudential system as a whole can be regarded as an ethical obstacle to biomedical studies and conscientious managing of genetic information. It also seeks to safeguard human dignity and to ensure international sharing of scientific information, fair access to the results of scientific research, and to prevent any improper use of sensitive genetic information.

Challenges for the Regulation of Biomedical Research and Genetic Data Sharing

This has turned out to be a positive trend, but raises many complicated matters for the international legal framework of biomedical research and the sharing of genetic data. The main issue is a lack of harmonization of jurisdictions. Definitions, ethics and procedures for its implementation vary from country to country. This leads to inconsistencies in conducting biomedical research in different countries of the world, the distribution of genetic information, and the protection of it.

A further issue of concern is the need for informed consent in the era of 'big data' and 'trans-border studies. The classic theory of consent is arguably ill-suited to address issues of re-use of information, long-term storage and future use (which is uncertain) of genetic information. There are also ethical and legal issues, such as the possibility that participants do not fully understand what they are agreeing to when they consent to broad or blanket use of their genetic information.

With growing cloud storage and international data transfer usage, it is important to protect and maintain the privacy of critical data and sensitive genetic information from unauthorized access, breach or misuse. It is difficult to ensure the security of personal data when it is outside the control of the country of origin, as not all countries have strict data protection laws. The legal environment is also sophisticated with regard to intellectual property rights. Genetics research may not be commercialized. Ethics of open science and equitable benefit sharing, especially when the research involves data on marginalized groups or developing countries. There is controversy as to the fair sharing of the fruits of such research.

Secondly, the existing rules and statements are not as effective due to the lack of effective enforcement mechanisms at the international level. Most international instruments are not legally binding and rely on voluntary compliance. This is not a good sign to try to discourage unethical practices. Finally, technological change is dynamic and can outstrip the development of legal requirements and create a gap in regulation, which will be exploited. We will have to be open and responsive to these new complex biomedical research issues.

Opportunities for the Regulation of Biomedical Research and Genetic Data Sharing

This new developing global legal system of biomedical research and exchange of genetic information offers different opportunities to improve global health, scientific studies and ethical systems. International cooperation is an opportunity. Another way to allow countries to cooperate more efficiently in mega research projects, including rare diseases, pandemics and personalized medicine, is through standard practices and ethical standards.

The second is equal access to biomedical innovation. Common legal ground may help to ensure a fair sharing of the benefits of genetic data collected from different groups of people. This will ensure that the medical therapies and technologies based on their data are available to the low and middle-income countries in the global research. The framework also provides an opportunity to enhance the rights and independence of individuals. Legal standards should create rights to informed consent, data privacy and withdrawal to empower the subjects and to ensure that the population has confidence in the biomedical research. As trust increases, the desire for people

to share their genetic data, to get more complete research results and data sets, also increases.

In addition, international harmonization of the data protection provisions could help in the cybersecurity and protection of genetic data. Secure architectures would enable institutions to easily share data across borders and play a key role in accelerating scientific discoveries while reducing the potential for misuse and abuse. There can be innovation wherever there is clarity in the IP laws. An intermediate solution that would allow the exchange and dissemination of knowledge while allowing for competition of the researchers' and developers' interests could protect them. This can be beneficial for the research of medical innovations.

Finally, the creation of a strong international legal order might also help to foster transparency and accountability. Unethical practices can be avoided by setting binding standards, by monitoring and by ensuring the research will be held accountable by the international community. All these opportunities are a way towards a more ethical, inclusive and innovative international biomedical future and sharing of genetic information.

Discussion

The regulation of biomedical research into genetic information is at a turning point in the world's legal systems. The balance and co-exist in the rules are increasing with the rapid development of science. National laws pertaining to consent, data protection and research ethics are marginal and unequal to laws. It's not uncommon for the cooperation between the borders to be difficult. There are many international instruments guiding, but with no enforcement and few instruments having a global presence. The difference raises ethical and legal issues, particularly with respect to vulnerable individuals and/or sensitive genetic data. Data ownership, data secondary use and anonymization are debatable. This has resulted in a developing trend towards developing international standards that are comprehensive and that take into account the promotion of research, but also protect the rights of individuals. It would be a universal legal system that would foster confidence in biomedical research, promote cooperation and enhance the just distribution of benefits. But it is difficult to strike a deal with a country that has different legal traditions, economic priorities and culture. Now it is aimed at the development of flexible and adaptive structures, which at the same time allow local autonomy but with global consistency. Multilateral dialogue, the involvement of stakeholders and good institutional management should be encouraged for this purpose. Biomedical research is the future of health care, and yet, it should not be a choice whether to regulate the practices in international law, but it should be a necessity.

Conclusion

Inter-regional regulation of biomedical research and exchange of genetic data is essential for maintaining ethical practice, respecting individual rights of people and empowering the world's scientific community. As genetic research is becoming more complex and crosses borders, legal differences can cause significant ethical, legal and operational challenges. The absence of a common international legal system, combined with the various elements of the consent procedure, data privacy and ethical requirements, can compromise the validity of the study and the welfare of the subjects under study.

A single, uniform regulatory framework can contribute to transparency, accountability and uniformity in the management of precious genetic information, especially in international research collaborations. A more effective and binding international regime is necessary to tackle these issues, although soft law instruments and regional agreements have tried to. In the future, balancing innovation and moral responsibility will be a system that will be achieved by international cooperation, legal harmonization and the involvement of stakeholders. It is a very important infrastructure in the research of Biomedical sciences, in a fair and sustainable manner.

Recommendations

To enhance the effectiveness of the international legal system in the field of biomedical research and the sharing of genetic data, different strategic

suggestions are to be considered. First, every nation needs to be assisted in regulating the collection, storage, use and sharing of genetic data in a common ethical and legal framework. On the one hand, standards must protect individual autonomy, informed consent and privacy, and on the other hand, promote access to the benefits of research. Thirdly, the international cooperation should be institutionalized in the form of treaties and conventions, which will outline the responsibilities, liabilities and data management between the concerned countries. There could be a platform available worldwide for regulation and/or collaboration in order to coordinate and enforce compliance (and even solve conflicts and share best practices on the fly). Third, capacity-building programs will be developed specifically in the developing countries to enable them to achieve international standards in research and become partners in international biomedical programs. This also involves training in the area of law, technical support and ethical review systems.

The legal framework should enable transparency, which includes transparency regarding the research goals, data processing procedures and data sharing contracts. If there were some sort of world database of common information where only certain people could have access to it, then they wouldn't be infringing on anyone's privacy when they're conducting research on that information. Finally, legal frameworks should be flexible and should enable their adaptation to new bioethical challenges and technological developments when they arise, in order to ensure long-term, responsible innovation in biomedical sciences.

Research Limitations

The study has valuable implications for international law relating to biomedical research and the sharing of genetic information. However, it comes with its disadvantages. The first is that there are no easily accessible, reliable global data, and second, the different regulations and enforcement across jurisdictions. This plasticity limits the possibilities for a purely comparative analysis and can lead to generalizations that are not universal. Also, some laws, especially in developing countries or other non-English speaking countries, were not easily accessible or poorly documented, which affected the completeness of this study.

Another limitation is the dynamic nature of biomedical technologies and data-sharing practices. Often, the legal frameworks are not as modern as the scientific breakthroughs, and the assessment that is carried out today may be outdated in the future. Moreover, the law is flexible in terms of ethics and culture, and this constitutes an obstacle to the harmonization of practices at the international level. Finally, this study focuses on legal frameworks, but to a lesser extent on technical and institutional barriers to implementation, which are also important.

Research Implications

This study may be relevant to the policy-makers, legal scholars and international health organizations. It needs an international legal framework that would ensure the promotion of scientific progress and protect the individual rights, particularly with regard to privacy, consent and security of data. In this context, it is important to emphasize the need for legal protection to be built into the procedures of biomedical research to improve the ethics of research at the cross-border level. The paper emphasizes the need to develop the capacity of developing countries to establish legal frameworks for global data sharing programs. It also warns the stakeholders of the risk of non-coordinated and outdated regulations, which can be abused and violate ethics. Moreover, the study presented in this work will aid in the formulation of universal standards, which will facilitate the development of international cooperation while respecting the sovereignty of the countries and the freedom of the people. Finally, the research work provides guidance on how to take the discussion on global governance of biomedical research and genetic data management in the right direction with a focus on equity, transparency and accountability.

Future Research Directions

The future research agenda for international regulation of biomedical research and the sharing

of genetic resources should be directed towards the establishment of a more comprehensive set of international standards that will benefit both the technological revolution and various moral principles. Analyzing the differences between world legal systems through their comparison could assist in discovering the best practices and the spots where the law is deficient. The potential research topics will explore the confluence of AI implementation and genetic data, which, on the one hand, raises new legal and ethical issues, and on the other hand, calls for quick regulation.

More research is required to understand the mechanisms by which international organizations coordinate laws and settle disputes among the participating countries. A thorough analysis of mechanisms of cross-border data flows, particularly in low- and middle-income countries, can also help to develop fair policies. The research also needs to study what is the implications of the emerging technologies like gene editing and synthetic biology in the context of international law. Finally, future research should aim to keep the legal frameworks up-to-date with scientific progress and on the protection of human rights.

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