INTERNATIONAL FRAMEWORK ON THE ETHICAL AND LEGAL ISSUES OF BIOMEDICAL RESEARCH

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ABSTRACT

The public and society are becoming more concerned as a result of new ethical issues that are being brought up by advances in biomedical science and technology and its use in the practise of medicine. The public is voicing its alarm over potential misuse in scientific research and biomedical technologies. The latest developments in science and medicine are reason for celebration and joy, but they also require careful consideration of dangers vs benefits and raise some delicate and challenging ethical questions. These must be handled with the highest care and extreme sensitivity to human values, together with the creation of ethical standards for clinical research. The purpose of this article is to provide a quick overview of the many international guidelines and laws that apply to matters such as informed consent, confidentiality, giving incentives, and different types of research misconduct. The safety of the patients who voluntarily consent to participate in the trials is protected by ethical strategies, which guarantee the integrity of the research findings. Additionally, ethical guidelines shield participants from the research team's exploitation or unfair treatment. The recommendations cannot be comprehensive or exhaustive due to the complexity of the topic. They must be updated to reflect the advancements made in science and technology. The Nuremberg Code, the first international code of ethics for human subjects' research, was created in response to the atrocities carried out by Nazi research physicians that were exposed at the Nuremberg war crimes trials. The Nuremberg (1947) convention established guidelines for conducting human experiments, placing a strong emphasis on the subjects' free consent. By adopting the "Declaration of Helsinki," which outlined ethical standards for research involving human beings, the World Medical Association (1964) went one step further to relieve society. Respecting the dignity, rights, and wellbeing of study participants requires adherence to principles of ethics. The paper shed light into the importance and possible dangers of biomedical research, the ethical and legal issues surrounding it and the international frameworks which regulates the ethical conduct followed in these researches.

Introduction

The rules of conduct for scientists who perform research are governed by research ethics. Respecting the dignity, rights, and wellbeing of research participants requires adherence to ethical standards. Legal and ethical issues form an important component of modern research, related to the subject and researcher.[1] In order to ensure that the proper ethical standards are being observed, an ethics committee should review all study involving human subjects. The central focus of ethical review is discussion of the ethical concepts of beneficence, justice, and autonomy. In order to promote ethical standards and appropriate methods of review for every research project involving human subjects, WHO collaborates with Member States and partners. The Research Ethics Review Committee (ERC) at WHO makes sure that only the most ethically acceptable research is supported by the organisation. Every research project involving human subjects that has received financial or technical support from WHO is reviewed by the ERC. The International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS 2016) and the World Medical Association Declaration of Helsinki (1964), both of which were most recently amended in 2013, serve as the ERC's guiding principles.

Concerns about the ethical and legal issues concerning the conduct of clinical research involving human subjects have long been voiced by policymakers, attorneys, scientists, and doctors. The standards and laws governing biomedical research currently vary greatly. While some countries have laws that must be followed, others rely on administrative or ethical standards in the workplace. Although obtaining consent before receiving medical treatment is typically required by law in research involving both adults and children, there is no set standard for how much information should be provided to patients to guarantee that their consent is sufficient or informed. Additionally, there is no clear agreement on the situations in which consent may be waived. The procedures and forms used to seek consent vary. The same is true for other regulatory mechanisms, such as the nation's research ethics committees' legal status, function, and composition. The law is lagging behind science in the rapidly evolving field of research involving the application of new biotechnologies, such as stem cell research or study on human tissues. As policymakers work to agree on guiding principles for the governance of biomedical research, there is often a legal gap. It has also been questioned whether universal

[1] Camille Yip, *Legal and ethical issues in research*, 60(9) INDIAN JOURNAL OF ANAESTHESIA, 684-688, (2016).

standards of research can be developed regardless of disparities in wealth and access to healthcare due to pharmaceutical companies' conduct of clinical trials in developing nations that lead to the discovery of drugs that are then out of the reach of the local populace.

The Declaration of Helsinki outlined moral guidelines that apply to clinical studies involving human subjects. Clinical research seeks to improve clinical practise and help patients in the future by methodically gathering and analysing data from which generalizable conclusions can be made. To ensure that the research is carried out both ethically and in accordance with local regulatory policy, it is crucial to be familiar with Good Clinical Practice (GCP), an international quality standard offered by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)[2], or the local version, GCP of the Central Drugs Standard Control Organization (India's equivalent of the US Food and Drug Administration)[3]. The definition of sponsors' and investigators' responsibilities, the consent process monitoring and auditing procedures, and the protection of human subjects are a few of the important GCPs in research.

In general, honesty, integrity, and social responsibility are considered to be the fundamental ethical standards. Yet, it has a number of viewpoints in regard to biomedical research and publication, for which a researcher needs to be aware and sensitive. A few of these are:

(i) Thorough analysis in the design, collection, and analysis of research data.

(ii) Preserving the confidentiality of study subjects and personnel files.

(iii) Always citing your sources; utilising scientific information without doing so constitutes plagiarism.

(iv) Focus on knowledge and research advancement rather than one's career. Resist the temptation to publish the same research again without making the required disclosure in various journals or languages.

(v) Safeguard the research participants/patients, particularly the most vulnerable group, by reducing risks and optimising benefits. To protect the interests of the human subjects involved

[2] ICH Harmonised Tripartite Guideline, Guideline for Good Clinical Practice E6(R1), Current Step 4 Version International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (2016). Available at http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/goodclinical-practice.html

in the study, the patient's or the guardian's informed consent must be given in the presence of witnesses.

(vi) Only conduct research using animals if they are truly required and worthwhile. Reduce misery and discomfort during the experiments by exercising due care and compassion.

"Research misconduct" is the act of engaging in academic behaviour with the goal to mislead while violating the aforementioned ethical standards. It includes "falsification, plagiarism, or fabrication.

History

Seeing much of the history of medical ethics as a commentary on the ethical concerns that have developed in biomedical research with human subjects during the past 75 years is one potential approach to structure the story of the origin and evolution of medical ethics. Edward Jenner did not have to deal with a complex regulatory system when he first introduced the smallpox vaccine. The rabies vaccine developed by Pasteur and the chemotherapeutics created by Ehrlich also emerged during a time with limited regulations. Due to the demands of war, penicillin was able to quickly make its way to the clinics on the front lines[4]. But over time, particularly following the thalidomide tragedies of the 1960s, expensive regulatory mechanisms have been introduced. While it is evident that human subjects must be involved in scientific studies in order for medical advancement to occur, research ethics often concentrates on situations when vulnerable individuals were hurt or other moral issues occurred. It is important to remember that controversial trials are frequently conducted by researchers and organisations who initially believed they were advancing public health and welfare. This is in contrast to the work of malicious "scientists" like Josef Mengele. Studies like Tuskegee (Jones, 1993), Willowbrook (Murphy, 2004), the Kennedy Krieger Institute Lead Paint Study (Mastroianni and Kahn, 2002), and some of the AZT preventative studies in underdeveloped nations are well-known examples of controversial research.[5] It is obvious that doing research on humans can lead to a variety of moral dilemmas that call for ethical assessment and analysis. For example, under what circumstances can using human subjects for research be justified? What does "informed consent" mean and encompass?

[4] Mariya Lobanovska & Guilia Pilla, *Penicillin's Discovery and Antibiotic Resistance: Lessons for the Future?*, 90(1) YALE J BIOL MED. 135-145 (2017).
[5] Marcel Verweij & Angus Dawson, *Public Health Research Ethics: A Research Agenda*, 2(1) PUBLIC HEALTH ETHICS, pp. 1-6(2009), https://www.jstor.org/stable/26644850.

The origin of modern international bioethics has been traced to the brutal abuse of human lives in the holocaust.[6] Medical researchers were found guilty of "crimes against humanity" at the Nuremberg "Doctors Trial" (1946–1947) on the basis of 10 ethical principles that were said to be fundamental and universally applicable to all ages and civilizations.[7] A growing number of initiatives were made in the decades that followed to formalise and codify a set of ideas that would have international approval. The World Medical Association (WMA) was established in 1947 to represent doctors and to advance medical professionalism and ethical standards around the world. The Geneva Declaration of 1948 was the first international declaration to outline the ethical duties that doctors have to their patients. A doctor's oath is included in the Declaration, which states that they would "not use my medical knowledge in a manner that is contrary to the laws of humanity and that I will practise my profession with conscience and dignity, with the patient's health as my primary consideration." At the moment of conception, the doctor must treat every human being with the utmost respect. The first International Code of Medical Ethics was adopted in 1949 in response to the Declaration of Geneva.[8] A brief description of a doctor's obligations can be found in the 1949 Code. These obligations include a responsibility to ensure that "any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest," "complete loyalty to the patient," "absolute secrecy on all he knows about his patient," and a list of practices related to conflicts of interest and financial benefits that are deemed unethical. In 1968 and 1983, the International Code was amended twice.[9] The 1983 amendment of the Code adds a new provision that patients' and co-worker's rights be respected. Also, the necessity to always keep in mind the obligation to preserve human life has been replaced with a weaker requirement.

The evolution of the Helsinki Declaration is contrasted with the global expansion of the bioethics movement, its influence on public policy, and the formation of national and international bioethics committees to control biomedical research. Nonetheless, the Declaration of Helsinki, which the WMA approved in 1964, has had and continues to have the largest influence on the international regulation of biomedical research in terms of practical effects. The Helsinki Declaration on biomedical research involving human participants

[6]Subhash Chandra Singh, *International Bioethics and Human Rights: Ethical and Legal Principles in Biomedical Research*, 5(2) JOURNAL OF THE INDIAN LAW INSTITUTE. 201-20 (2009), http://www.jstor.org/stable/43953439

[7] Ibid

[8] World Medical Association, International Code of Medical Ethics 109-111 (1949).

[9] WMA, International Code of Medical Ethics , adopted by the 3rd WMA General Assembly, London 1949 and amended by the 22nd WMA General Assembly, Sydney, Australia, 1968 and the 35th WMA General Assembly, Venice, Italy.

contains standards guiding trials. Since its start, it has undergone numerous revisions. Trials should only be conducted, according to these standards, "if the value of the objective is in proportion to the inherent risk to the subject," and "the interests of the subject must always take precedence over the interests of science and society." Ethics committees should be established to ensure that volunteers taking part in trials receive payment for liability expenses or compensation for losses incurred as a result of the trials, are educated about the procedure or medication being tested, and grant "informed consent." This isn't always the case in reality.[10] The Tokyo Declaration from 1975, Sydney Declaration from 1968, and Oslo Declaration from 1970 are also noteworthy. All of these declarations address ethical concerns in the practise of medicine and offer recommendations for medical professionals.

Issues related to the research participants

Human participants in research are primarily used as data sources. Protecting the "life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects" is the responsibility of researchers.[11] The Belmont Report also offers a methodology for analysis that uses three ethical standards to assess research:

1. Respect for people - the obligation to recognise autonomy and safeguard those with weakened autonomy
2. Beneficence is the principle of first doing no harm, then maximising benefits and minimising risks.
3. Justice - On a personal and societal level

Research misconduct is defined as the mistreatment of research subjects (no ethical review approval, failure to follow approved protocol, absent or inadequate informed consent, exposure of subjects to physical or psychological harm, exposure of subjects to harm due to unacceptable research practises or failure to maintain confidentiality). Fraud and deception are other examples of scientific misconduct.

Research Regulations: Limits and Problems

How should risks be weighed in relation to how crucial the study's aims and suggested methods

[10] JYOTSNA AGNIHOTRI GUPTA, NEW REPRODUCTIVE TECHNOLOGIES; WOMEN 'S HEALTH AND AUTONOMY 325 (Sage Publications 2000).
[11] World Medical Association. *World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects,* 310(20) JAMA. 2191–2194 (2103), doi:10.1001/jama.2013.281053.

are? Much effort has been put into developing, defining, and implementing rules for scientific studies involving human beings since the middle of the 20th century. The Nuremberg Code (1949), the Declaration of Helsinki (1964, amended 2008), and the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) are three important publications on the list of those that are significant. Although the significance of these guidelines for research practise should not be underestimated, they play a very little part in bioethical reflection. The codes should not be viewed as instruments for doing ethical analyses, but rather as regulatory standards for research, ideally built on a broad consensus and justifiable to both the scientific community and the general public. The critical moral issues that occur in medical research are only poorly addressed by the principles and their explanations. Such topics are still up for debate. Regulations work best when they are utilised to direct decision-making; they shouldn't take the place of reflection. It's crucial to recognise that rules can sometimes raise more difficulties than they resolve, for instance, regarding the ethical justification for the codes and the scope, purpose, and limits of the rules they contain.

International ethical guidelines on Medical Research

Medical research is necessary to identify the root causes of illness or to find novel approaches to treating or coping with pain or disease. The development of the appropriate ethical and legal norms frequently lags behind the science in the rapidly evolving field of research involving the application of novel biotechnologies, such as stem cell research on human tissues. Instead of being governed by statute, medical research on the human body is currently governed by a combination of administrative and professional rules. Direct case law on medical research does not exist. Therefore, it is necessary to infer from general legal principles and regulations in related fields, such as medical treatment, the potential liability to medical researchers. Despite without defining medical research, the Declaration of Helsinki outlines the acceptable justifications for research's conduct:

The improvement of preventative, diagnostic, and therapeutic methods as well as the comprehension of the aetiology and pathogenesis of disease are the main goals of medical research involving human subjects. The efficacy, efficiency, accessibility, and quality of even the finest tested preventative, diagnostic, and therapeutic procedures must be regularly examined through research.[12]

[12] The Declaration of Helsinki, paragraph 6

According to the human rights perspective, medical research should only be done on those who would directly or indirectly benefit from it. Any advantages granted to third parties were justified on the basis that they were a by-product of the advantages given to participants. So, the first rule of medical and surgical ethics is to never subject a human being to an experiment that could even slightly hurt him, even if the outcome could be extremely beneficial to research or, for example, to the health of others. There is a risk that classifying an intervention or procedure as an innovative or experimental treatment, "therapy," or "practise" could be used to justify a lower level of legal protection on levels of information and disclosure of risks than those appropriate for research, despite the fact that the distinction between experimental treatment and research is particularly important in regard to the specification of the legal obligations imposed on researchers. The Helsinki Declaration established an important difference between therapeutic and non-therapeutic research. According to Section II (2) of the 1964 Declaration, a doctor may only combine clinical research with professional treatment when it is therapeutically beneficial to the patient and the goal is the gain of new medical knowledge. The distinction between therapeutic and non-therapeutic research was, however, eliminated in the 2000 revision following a protracted discussion and amid worries from critics that the removal of the distinction would weaken the protection of research participants.[13]

1. The Declaration of Helsinki - Evolution of international norms

A close examination of the court decisions where the Helsinki Declaration has been cited in legal proceedings reveals that the Declaration's legal force is severely constrained by local procedural and substantive rules of law. The Declaration of Helsinki has frequently been cited as a key influence on the development of many international codes governing research on human subjects, but this is not always the case. The Declaration has been used by U.S. courts in a number of cases as a reference to international law norms governing the conduct of medical experiments, along with the International Covenant on Civil and Political Rights (1966). The Helsinki Declaration, like the prior codes, serves as a statement of ethical principles to guide physicians and other individuals performing medical research on human subjects. The domestic courts of several nations have acknowledged that, while if the Declaration of Helsinki is not an agreement between states and does not have the stature of a treaty, it can nonetheless be cited as proof of established international legal principles. The Declaration of Helsinki's practical value is mainly found in the influence it can have on the development of professional codes of

[13] Supra note 5.

conduct or, alternatively, the drafting of legal instruments that uphold its ideals in the field of professional self-regulation.

The authority of the Helsinki Declaration is weak and limited from a purely legal standpoint. The Declaration is a statement of professional ethical ideals and principles addressed to other members of the medical profession, as is evident from the Declaration's language. As stated in the Preamble to the original Declaration of 1964, these principles offer a set of criteria that would serve as a reference for doctors everywhere. The laws of their countries do not exclude doctors from their obligations under the criminal, civil, and ethical standards.[14] The Declaration of Helsinki (2000) substitutes the best "current" method for the earlier requirement that the control group be given the best "proven" diagnostic and therapeutic approach. The benefits, dangers, costs, and effectiveness of a new approach should be compared to those of the top preventive, diagnostic, and therapeutic techniques now available, according to paragraph 29. This does not preclude using a placebo, or no therapy at all, in trials when there is no established preventative, diagnostic, or therapeutic approach.

With the 2000 change, some critics expressed concern that the new wording, which replaced best "proven" procedures with best "current" approaches, was unclear. Does "best current" refer to a standard that is universal and only based on clinical factors, or does it refer to the best therapy that is currently being offered locally? If so, the standard may be based on the local, social, and economic conditions, which can differ from one location to another? If the first scenario were to occur, the best "current" standard would forbid the use of placebo controls in nations with little resources. If the latter, participants in the same trial in developed countries would receive whatever cutting-edge treatment is readily available locally rather than a placebo, and placebo controls might legitimately be employed under Helsinki rules in developing countries.[15]

2. The 2002 International Ethical Guidelines for Biomedical Research Involving Human Subjects

The third set of biomedical-research ethical standards released by CIOMS since 1982, the 2002 International Ethical Guidelines for Biomedical Research Involving Human Subjects replaced

[14] See the Preamble to the Helsinki Declaration, 1964.
[15]AURORA PLOMER, THE LAW AND ETHICS OF MEDICAL RESEARCH: INTERNATIONAL BIOETHICS AND HUMAN RIGHTS 47 (Routledge-Cavendish 2005).

the 1993 Guidelines. These were replaced in 2016 by the CIOMS publication of the International ethical principles for health-related research involving humans.

There are 21 guidelines with commentary in the 2002 text. A prefatory part that comprises an introduction, a description of preceding instruments and guidelines, a statement of ethical principles, and a preamble describes the historical context and the revision process. The components of the research protocol that must be submitted for approval by scientific and ethical review are listed in an appendix. The Declaration of Helsinki from the World Medical Association is also included in the appendices. The Guidelines mainly deal with the ethical justification and scientific validity of research, informed consent, vulnerability of individuals, groups, communities, and populations, equity regarding burdens and benefits, choice of control in clinical trials, confidentiality, compensation for injury, strengthening national or local capacity for ethical review, and the duties of sponsors to provide healthcare services.

Their scope is an accurate reflection of the developments, controversies, and changes that have characterised biomedical research ethics during the past two decades. The 2002 CIOMS Guidelines, like those of 1982 and 1993, are intended to assist nations in formulating national policies on the morality of biomedical research involving human beings, applying ethical codes to specific local conditions, and establishing or enhancing ethical review processes. Reflecting the circumstances and requirements of low-resource nations, as well as the consequences for international or transnational research projects in which they can participate, is a special goal.

3. The Convention on Human Rights and Biomedicine (CHRB)

A significant step towards harmonising international standards in the field of biomedicine has been taken with the adoption of the Council of Europe's Convention on Human Rights and Biomedicine (CHRB) (1997)[16]. The preamble's commitment to taking the necessary steps to protect human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine makes clear the Convention's goal to realise fundamental and universal values.[17] The aim must be balanced against the reality of the many forms and norms of global and European research regulation. The CHRB protects people and the human race against the "misuse of biology," ensuring that both the current and future

[16] Aurora Plomer, 'Medical Research, Consent and the ECHRB', in Garwood-Gowers et al. (eds.). Healthcare Law: The Impact of the Human Rights Act, 1998 313-30 (2001).
[17] CHRB, Preamble.

generations can benefit from advances in biology and medicine.

The goal of the CHRB is outlined in Chapter Article 1: Parties to this Convention should defend the dignity and identity of all human beings and guarantee that everyone is treated fairly with regard to other rights and fundamental freedoms when applying biology and medicine.

There is a specific chapter on scientific research in the CHRB. Article 15 affirms the freedom to conduct scientific research with restrictions to safeguard the human being's safety as stated in articles 16 and 17. The participant (or his legal representative) must voluntarily provide their informed, free consent in advance. The participant must get the necessary information regarding the goal and nature of the intervention, as well as its risks and effects (article 5). According to article 16(v), consent must be given expressly, clearly, and in writing. Article 16 outlines restrictions on research that are necessary to protect human participants. There is no substitute for human research that is as effective (see article 16(i)). The potential hazards must not outweigh the potential benefits of the research (article 16(ii)), and the subjects of the research must be aware of their rights and the legal protections that are in place to protect them (article 16(iv)). Article 16 (iii) stipulates that a research ethics committee had to have approved the research. Article 17 distinguishes between research that has the "potential to produce real and direct benefit" for the individual (article 17.19(ii)) and that has the "aim of contributing to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category afflicted with the same disease or disorder or having the same condition" (article 17.2(i)).

4. Fundamental principles applicable to human experimentation

The US Advisory Committee on Human Radiation Experiments (ACHRE, 1996) independently asserted that it had defined a number of universally applicable fundamental principles that may always be used to assess the ethics of human experimentation retroactively, if necessary. Six fundamental ethical principles were cited by the ACHRE as being mostly binding to societies of medical researchers throughout time and space.[18] The guidelines are:

1. One should not use individuals as merely a method of achieving the goals of others;
2. One should not deceive others;
3. One should not cause injury or put others in danger;

[18] Advisory Committee on Human Radiation Experiments (ACHRE), Final Report of the Advisory Committee on Human Radiation Experiments, chapter 4 at 1, (1996).

4. One should promote welfare and prevent harm;
5. One should treat all people fairly and with equal respect.
6. Self-determination should be respected.

The ACHRE distinguished between therapeutic studies without the subject's consent and non-therapeutic experiments without the subject's consent using the aforementioned ethical framework. They were considered to be violations of the Hippocratic oath, which at the time served as the cornerstone of professional medical ethics, in addition to the basic principles outlined above. The welfare principle, which states that one should increase benefit and prevent harm, is a core or fundamental premise for the conduct of research, is the last assertion made by the ACHRE. But, as was already mentioned, the principle is open to a variety of interpretations, some of which are debatable. The main ambiguity here rests on the absence of the clear explanation of whose welfare medical researchers are presumably under a moral obligation to promote: the individual's wellbeing or the welfare of society? The two must go together, and while the former may be uncontentious, the latter is not.

5. International Ethical Codes relating to consent

International ethical codes and human rights agreements generally agree that medical researchers must first obtain the participant's free and informed consent. Since its initial ratification in 1964, the Helsinki Declaration has included the rule of consent in each version. The 2000 version reads as follows:

In any research on humans, each potential subject must be adequately informed of the study's aims, methods, source of funding, and any potential conflicts of interest. It also must be aware of the researcher's institutional affiliations, as well as the anticipated benefits, risks, and discomfort. The participant should be made aware of their ability to refuse to participate in the study at any time without suffering any consequences. The doctor should then seek the subject's freely given informed consent, preferably in writing, though non-written consent must be legally documented and witnessed when the subject has been certain that they have received the information.

The International Covenant on Civil and Political Rights (ICCPR) (1966), which prohibits torture and other cruel, inhuman, or degrading treatment or punishment, has endorsed it. In particular, no one shall be the subject of a medical experiment without his informed consent. Article 5 of the CHRB simply reaffirms an accepted international principle by stating that any

intervention in the sphere of health "may only be carried out after the individual concerned has provided his or her free and informed consent to it." Thus, whether or not the individual has been harmed, a violation of article 5 occurs anytime the individual's consent has been obtained by deception or misrepresentation. The right that is protected includes the freedom to decide whether or not to take part in a project. According to a widely accepted principle, a doctor is required to obtain the patient's consent before beginning any treatment. The fundamental principle of respecting the patient's autonomy and right to decision-making is the foundation of the doctor's obligation to get consent for treatment.

According to Lord Donaldson in R v. T[19], a person has the right to "live his own life how he likes, even if it damages his health or causes him to pass away before his time." This means that every adult with mental capacity has the "full freedom to choose whether to consent to medical treatment, to refuse it, or to one treatment over another, whether the reason is reasonable, irrational, or there is no reason at all." The Court of Appeal has often reaffirmed this right in cases. Re MB[20] involved a pregnant lady refusing treatment when it endangered both her and her unborn child's lives. Re W[21] involved a prisoner who, knowing full well that septicaemia would follow and cause his death, refused treatment for a leg wound. The Court of Appeal upheld the right of a severely crippled but mentally competent woman to reject life-saving treatment in Mrs. B. v. An NHS Hospital Trust[22].

6. Human dignity in international human rights instruments related to biomedicine

The phrase "inherent dignity of the human being" is frequently used in the preambles of international human rights instruments, particularly those pertaining to the biomedical sciences. Human reproductive cloning is one of the techniques that violates human dignity, according to the UNESCO Universal Declaration on the Human Genome and Human Rights (1997). According to the Universal Declaration, no one shall be the target of genetic discrimination that is intended to violate or has the impact of violating their human rights, basic freedoms, or dignity.[23] The declaration further states that genetic information that is linked to a specific individual and kept for research or any other purpose shall be kept private in accordance with the rules established by law. In accordance with the application of biology and

[19] (1992)4 All ER 649.
[20] (1997) 2 FLR 426.
[21] The Independent, June 17, 2002; Lawtel 2(7) 2002.
[22] (2002) 2 All ER 449
[23] See art. 6 of the UNESCO Universal Declaration on the Human Genome and Human Rights (1997)

medicine, Article 1 of the CHRB declares the necessity of safeguarding the dignity and identity of every human being and ensuring that everyone is treated with respect for their integrity and other fundamental rights. Nonetheless, despite a prominent mention of human dignity in the CHRB, there is still a great deal of confusion over the precise definition, applicability, and function of the idea as a fundamental value of a specific right.

7. Ethical and legal principles applicable to research on human embryos

The research on embryonic stem cells has caused controversy all around the world recently. The search for an ethical consensus and the ethical legitimacy of such research have been major topics of discussion up to this point. The medical communities disagree on whether and under what conditions processing of embryonic stem cells is appropriate. Stem cell processing, and in particular the generation of stem cells when the embryo from which they originate must be destroyed, is ethically and scientifically debatable and is prohibited in many nations. Human reproductive cloning is one of the "practises which are opposed to human-dignity," according to the UNESCO International Declaration on the Human Genome and Human Rights (1997).

The British Government established a Committee of Inquiry into Human Fertilization and Embryology in England in July 1982 for the purpose of making various recommendations. Members of the committee were drawn from a variety of disciplines, including medicine, law, theology, and the natural and social sciences.[24] In addition, it was mandated that policies and protections be applied, as well as examination of the social, ethical, and legal implications of recent and anticipated advancements in human fertilisation and embryology-related medicine and science. The Warnock Report was released as the conclusion of these discussions.

The guideline states that no live human embryo obtained from in vitro fertilisation, whether frozen or unfrozen, may be kept alive, if not transferred to a woman, beyond fourteen days after fertilisation. This is in reference to experiments on embryos developed from women's eggs. The Voluntary Licensing Authority (VLA) in Britain first used the term "pre-embryo" in 1985 to describe an embryo that has been fertilised outside of a woman's body for up to 14 days. To make embryo research acceptable, it was accepted. Human embryo research is allegedly an insult to human dignity and a violation of the right to life of the human embryo, according to opponents of embryonic stem cell research.

[24] Marry Warnock, A Question of Life: The Warnock Report on Human Fertilization and Embryology, 4 (1985).

The Human Fertilization and Embryology Act, 1990 was enacted in the United Kingdom as a result of the Warnock Committee Report to protect embryos' interests. The Human Fertilization and Embryology Authority (HFEA) came into being in 1991. This statutory body advises the public and the government on ethical and scientific challenges resulting from advancements in assisted reproductive technology. It also controls the use and storage of embryos and gametes outside the human body. The Human Fertilization and Embryology Act of 1990 serves as the HFEA's primary source of guidance.

In the United Kingdom, it is against the law for nuclear replacement technology-assisted embryo development to result in the birth of any foetuses or children. According to the law as it exists, the only uses of this technology may be non-reproductive ones. The development of in vitro stem cells to shed light on how damaged human regeneration may be created without risk of rejection is an example of the reproductive use of this technology. Although ethical issues are highlighted by this possible use of nuclear replacement therapy, they are very different from the issues raised by reproductive cloning.

8. Medical experimentation on the dead

In order to enhance our understanding of the causes of disease and mortality, scientific research on human tissue or body parts is required. Nonetheless, it is necessary for the scientific community and the medical profession to function within socially acceptable parameters. The primacy of social wellbeing over individual rights is a logical presupposition of utilitarian and welfarist concepts of beneficence. Therefore, in actuality, utilitarianism could support the instrumental use of human bodies for the good of society as a whole. The idea of human dignity is also inherently undefined and has a wide range of applications.

The idea of human dignity requires that there be a special approach to treat people that is proper and fitting to them in the situation of disposing of human bodies (in a way, for instance, which would be different from the appropriate handling of a material object, mineral, an animal or a plant). So, social beliefs about the purpose and worth of human life have a significant impact on what dignity and respect in the disposal of a human corpse demand. Such ideas have no relevance when dealing with physical objects from a scientific standpoint. The removal and use of human tissue from the dead for scientific reasons is not addressed in the CHRB of the Council of Europe.

Nonetheless, the European Convention on Human Rights and Fundamental Freedoms (1950) does contain restrictions on privacy and degrading treatment, which had previously been thought to apply only to the living but may potentially even reach the deceased. The greatest way to ensure proper legal protection for the deceased while acknowledging the legitimacy of certain sorts of intervention with and research on human bodies and body parts is through the human rights approach. Based on this, there is no question that while conducting scientific research on human tissue or organs, the rights of the deceased should be fairly weighed against the interests of society. Many human rights instruments were believed to be in jeopardy because of precisely this kind of societal interest.

Conclusion

Every medical research involving human beings requires that the researchers have a thorough understanding of the law and professional ethics. A legal or ethical framework that aims to define fundamental and universal principles and rights in medical research is required at the national level. For the sake of the general good, national legislation must adequately justify disregarding individual autonomy and wellbeing. Furthermore, there are strong arguments against the notion that the legal framework of national and international regulations is adequate to stop practise. The lack of comprehensive regulatory frameworks to oversee and regulate adherence to the rules is a major source of worry. On a national level, the Research Ethics Committees (RECs) are tasked with reviewing research programmes to screen out those that don't adhere to international standards. Fundamental human freedoms and rights cannot be circumvented or limited in any way by existing and dominating cultural and ethical norms, as required by the universality rights. The benefits of science and technology cannot be limited to millions of people due to cultural views in specific societies or sectors. It is imperative that medical ethics are updated as soon as possible in order to stay up with scientific developments in the practise of biomedicine. International rules are preferred so that scientific knowledge is shared by all nations rather than being confined to one. Although it is true that medical research involving human beings can be abused and misused in a variety of ways, the answer does not rest in discarding the medical research but rather in regulating it for the sake of humanity.