12.1 Introduction

The research being carried out should be essential for the advancement of knowledge that benefits patients, doctors, and all others in aspects of health care and also for the ecological and environmental well-being of our green planet and ecosystem. Scientifically ethics are the moral values of human behavior and the principles which govern these values. Every profession is bound by code of ethics (Greek word ethos meaning customs or character), and the essence of medicine and clinical research moral community dates back to Hippocratic Oaths (Gasparetto et al. 2018; Jameton 2013; Tarzian 2013). This word of honour is guide for the physicians on practising professional ethics and mandate that’s for profession, would prescribe only beneficial treatments, refrain from causing harm or hurt to his or her patients and would place the interest of their patient ethical and of our own interests. The situation becomes challenging for doctors when he/she assumes the role of a researcher. The doctor (researcher) serves both the roles, and at times, the zeal of an investigator has the potential to cloud the morality of the physician inside. History has its store in numerous instances when the enthusiasm for knowledge breached the principles of ethics (Beauchamp and Childress 2013). Thus, it was realized that the code of ethics for clinical research was needed, and good clinical practice guidelines for human research was framed. In any clinical practice, doctors pledge to treat every individual equally, irrespective of their age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing, or any other associated factors, since when it comes to research that pledge is blurred at times, and it is forgotten that the subject for research is also patients who has put their faith in the doctor for their treatment (White et al. 2001; Benatar 1998; Clinical ethics revisited by Peter Singer et al. 2001). Medical science is one discipline where the advancement of knowledge is hugely guided by research, and humankind has benefitted from many experiments. However, benefit and risk are the two faces of the same coin. If there is no loss, there is no gain; but the risk or loss is assumed by individual or participants of research, and benefit or gain is reaped by a human population, who did not have to bear that risk and to ensure all the participants gets fair treatment that he or she expects from his or her treating physician (Carpenter Jr et al. 2000; David 1994; Frankena 1973). Scientifically ethics is pluralistic, there can be disagreement among individuals about what is right and what is wrong, and even they agree, the reason can be different. The ethical word will be signifying the meaning of full-blown of research and novelty.

The first step in the evolution of ethics is a sense of solidarity with other human beings

Prof. Albert Sweiter
12.2 Ethical Rationality

Many medical research programs would cover long-ranging effects of ethics in manifold critics and pitfalls for selection of problems, study design, patient selection, and submission process, etc. The researcher is willing to formulate the study protocol of clinical research since the researcher should familiarize and have in-depth knowledge of ethical perspective and patient management during the study intervention. Many of the clinicians and researchers are not aware of ethical regularity and guidelines, then how to select the problems, what are the rules or framework presented in the ethical guidelines, confidentiality, legality, and dignity, and autonomy. In this aspect, the present chapter aims to describe various salient features of ethical guidelines and also describes new advanced and revised framework formulated at international and national standards (Agich 2001; Grisso and Appelbaum 1995; Hippocrates 1780). The present section will benefit the clinicians, research beginners, policymakers, and drug manufacturers for their research work at institutional level.

12.3 Principles of Ethics in Medical and Clinical Research

Hippocrates was the first physician to define the ethical principles of research in human. The following principles still valid today (Fig. 12.1).

12.3.1 Autonomy

In the human being tradition, the view that individual autonomy is a basic moral, ethics, and faith is very much a modern development. Putting moral weight on an individual’s ability to govern themselves, independent of their place in a metaphysical order or role in social structures and status of living is very much the product of the modernist humanism of which much contemporary moral and medical philosophy is an offshoot. We should respect the autonomy of the participants or their representatives for drug trials, the research participants should be aware of the nature of research and probable consequences of the clinical experiments and then make an independent choice without the influence of the treating doc-
tors, whether to take part in the research or not. When the research treats any community or group of persons as research participants, these principles of voluntariness and informed consent should apply to the community as a whole and also to each individual member who is the participant of the research or experimental group (novelty). All participants participated in drug trial should need to understand their consents and about treatment induction, duration, harmful effects, and overall legacy of the experimental research.

12.3.2 Beneficency

Beneficency is a concept in research ethics which states that researchers should have the welfare of the research participant as a goal of any clinical trial. In this regard researcher should maximize the economic and health benefits and minimize the harms, the clinical research always focuses on the objectives of human and animal interventions. The health benefits are very important for us to make use of our available resources from the green planet to maintain the overall wellbeing of individuals. The logic of beneficency dealt with quality of life (QOL) during the study period. In this pragmatic approach, the research should always maximize the health benefits and reduce the risks, e.g., the people living with cancer, treating with new trial, the atomicity of the research should always focus on the health concern of the subjects and on the other hand minimizes the side effects of drug. It is required that the procedure will be provided with the intent of doing good for the patients involved. When the demands that create research, the health-care providers will develop and maintain soft skills, knowledge of updating patients on virtual basis (training), etc. Consider individual circumstances of all patients, and strive for net benefits of patients and ended in welfare, many clinical researchers formulate new revised guidelines in accordance with international standards. All health-care providers must strive to improve their patient’s health, to do the most good for patient in every situation, what is good for one patient may not be good for another, so each should be considered individually.

12.3.3 Nonmaleficence

As per the legal perspective, non-maleficence is a practice in which physicians must refrain from providing ineffective treatments or acting with ill will toward patients. But since many beneficial therapies have serious risks, therefore, this principle, offers a little useful guidance to physicians. Doctors should attempt to avoid any act or research plan that would harm the patient or violate patients’ trust and human values and ethics during experimental trial. In modern health care and research, value conflicts arise where often there appears to be no clear consensus as to the right thing to do. These above cited conflicts makes many problems requiring moral decisions, and necessitate a choice between two or more alternatives, e.g., Should a parent have a right to refuse immunization for his or her child. Does we assess the public safety supersedes an individual rights and another example, COVID 19 outbreak vaccination trial solely depends on human values and ethics, researcher should focus the health-care needs and maintain the dignity of individual patients, the patient does not right to refuse the testing of COVID19 because the requisite intervention comes under ethical perspective of the patients on public domain and safety of the human community at globe.

The researcher should be concerned about the following points:
- First do no harms to the patient of COVID 19 from the excising treatment and social mobility.
- Maintain overall sanctity of life at all time.
- Be aware of the doctrine of double effect, where treatment or testing intended for good unintentionally causes any harm.

12.3.4 Justice and Confidentiality

The researcher should maintain the privacy of patient information, research plan, and the outcome of the research, equitable distribution of research risks and benefits. The justice is a complex ethical principle, with meaning that range from the fair treatment of individuals to the equitable allocation of health-care amounts and resources. It is concerned with equitable distribu-
tion of benefits to individuals in social institutions, and how the rights of various individuals are realized. Allocating scarce medical resources and also researcher or clinician should be able to justify the actions in every medical situation or follow-up visits of the patient. The general rights of ethics are presented in (Fig. 12.2).

Some of the following ethical questions would be aroused from the public interest, the followings questions and intervention are kept in mind, and refer necessary guidelines for further follow-up actions, the decision can be taken place at right time with the consent of judicial law (Fig. 12.3).

1. Should children with serious birth defects be kept alive?
2. Should be allowed an abortion for any reason?
3. Should terrorist be tortured to gain information possible saving hundreds of lives?
   (a) Should health-care workers be necessary to HCQ PEP drug for protection of COVID19
   (b) Organ transplantation and stem cell therapy for COVID19?

As per the practical insight, we describe the research ethics in a clinical prospective. The researcher should intervene to address the following key points before induction of research:

1. To understand and anticipate the current health literacy landscape as it pertains to clinical research on broad perspective,
2. To attempt to address the barrier for adoption of available resources and health literacy of the participants in the context of ethical perspective and strengthened the clinical research-related communications,

3. To mitigate the opportunities for sponsors and funders, investigators, and their study teams, and institutional review board can integrate health literacy throughout the clinical trial life cycle from recruitment, and informed consent should be obtained from the participants,

4. To establish electronic virtual-based data collections from the different study sites that are relevant to multiple stakeholder communities, including research intervention or subjects.

The clinical and scientific standards for carrying out biomedical research on human subjects have been developed and established in International guidelines, including the following:

1. Declaration of Helsinki,
2. CIOMS: International ethical guidelines for Biomedical research involving human subjects, and
3. WHO and ICH guidelines for good clinical practices.

### 12.4 Historical Milestone of Medical Ethics

1932–1972: Tuskegee experiment on syphilis (Hippocrates 1780)

1939–1943: Nazi Nuremberg experiment

1944–1974: Human radiation experiment by USA

1946: Nuremberg trail of doctors responsible for the Nazi experiment

1947: Nuremberg code outlining ethical principles required for research

1948: US adoption of universal declaration of human rights

1953: NISH policy, the first UD federal policy introducing independent review to examine research, forerunners of IRBS

1963–1966: Willow brook study, involving hepatitis research on mentally retarded children, raising issues access to care, consent, and coercion

1964: Declaration of Helsinki International agreement recommendation for the ethical

1972: Public exposure of Tuskegee syphilis study

1974: First federal protection for human research participants

1979: Belmont Report promoting three principles for research

1980: Food and Drug Administration Regulation (CRF 21(50))

1982: Council for International Organization of Medical Sciences (CIOMS) publication of the international ethical guidelines for biomedical research involving human subjects

1985: US Public Health Service Task Force on Women’s Health Issues export encouraging inclusion of women in research

1990: Society for women’s health research

1993: Public exposure of US human radiation experiments

1993: NIH revitalization act mandating inclusions of women and minorities in research

1993: NIH office of research on women’s health

1997: Food and drug modernization act (FDAMA) requiring NIH and pharmaceutical industry to develop guidance on the inclusion of women and minorities in trails

1998: Pediatric rule passed by congress, stipulating that new drugs for children must include specific pediatric labeling information

2000: Further publicized ethical abuses promoting establishment of the office of human research protection

2000: National commission for the research protection of human subjects of biomedical and behavioral research (Fig. 12.4)

### 12.5 National Guidelines

ICMR: Ethical guidelines for biomedical research on human participants

Indian GCP guidelines

Principles of precaution and risk minimization states that due care and caution must be taken at all stages of research to ensure that the research participants and those affected by it including community are put to minimum risk, suffer from no known irreversible adverse effects (ICMR 2006).
12.6 Declaration of Helsinki

The World Medical Association has developed the declaration of Helsinki; word of honour—it is a statement of ethical principle to provide certain guidance to physicians and researchers in biomedical research involving human subjects. The oath of Helsinki has involved many perpetuates and assimilates regularity guidelines. The principle aims to maintain the dignity of the participants and work ethics of the researcher. The principle describes that the research is a duty of the physician in medical research to protect the life, health, privacy, and dignity of human subjects, involving ethics he must confirm to generally accepted scientific principles with appropriate caution, and the research should be exercised in the conduct of research which may not affect the environment. The design and performance on each experimental procedure involving human subjects should be clearly formulated in the experimental protocol. All research protocols should always contain a brief statement of ethical considerations and should indicate compliance of drug safety and efficacy in the interest of well-being of participants; the rules are always laid down by the institution pledge in association with FDA and national standards (Humphreys et al. 2014; Harish et al. 2012; Jonsen et al. 2010; Kim et al. 2001). The concerned institution should establish the independent committee and confirm with laws and regulations of the country in which the research experiments are performed, committee’s right to monitor ongoing research subject to upheld scientific standards and human ethics. Subjects must be volunteers and informed consent is obtained from the participants. Every precaution should be taken at the right time and respect the privacy of subjects, confidentiality of the participants or subjects.

As per the FDA and national guidelines, the following ethical review board functionally performed the duty to maintain international and national standards of biomedical research.

IRB: Institutional Review Board
ERB: Ethics Review Board
REB: Research Ethics Board
12.6.1 Declaration of Medical Researcher, Professional Doctors

At the time of registration, each applicant shall be given a copy of the following declaration by the registrar concern and applicant can read and agree to abide by the same.

I solemnly pledge myself to consecrate my life service of humanity.

Even under threat, I will not use my medical knowledge contrary to the laws of humanity.

I will maintain utmost respect for human life from the time of conception.

I will not permit consideration of religion, nationality, race, party politics, or social standing to intervene between my duty and my patient.

I will practice my profession with conscience and dignity.

The health of my patient will be my first consideration.

I will respect the secrets which are confirmed in me.

I will give to my teachers the respect and gratitude which are their due.

I will maintain my all means in my power, the honor and noble tradition of medical profession.

I will treat my colleagues with all respect and dignity.

I shall abide by the code of medical ethics as enunciated in the Indian Medical Council.

I will make these promises solemnly, freely, and upon my honor.

12.7 IEC Institutional Ethical Committee

It is an independent body constituted for IEC, appointed medical, nonmedical, and nonscientific members whose responsibility is to ensure the protection of rights, safety, and well-being of human subjects involved in the trails by, among other things, reviewing, approving, and providing continuum development of trail protocol and amendment issues on the basis of international standards. The structure of IEC constituted 8–12 members, specifically, the chairperson should be preferably outside the institution to maintain the independency of the committee. The member secretary should be appointed by the concerned institution, and he conducts the business of committee regularly (Fig. 12.5).

12.7.1 Function of IEC

1. To provide competent review of all ethical aspects of the research project
2. Undertaken review free from any bias and influence
3. Provide advice to the researcher on all aspects of welfare and safety of research intervention
4. To protect dignity rights and well-being of the potential research participants
5. To ensure universal ethical values and international scientific standards in terms of social community values and customs

![Hierachical organogram of IEC](image-url)
6. To assist in the development and the education of research community responsive to local health-care requirement

**12.7.2 Document Submission**

1. Trail protocol (prescribed format)
2. Patient information sheet and informed consent form
3. Investigator brochure
4. Principle investigator CV
5. Insurance policy/compensation for participants
6. Investigators agreement with the sponsors (Fig. 12.6)

**12.8 Institutional Review Board (IRB)**

An institutional review board is a review committee that was established on international standards which helps to protect the rights and welfare of human research projects. The IRB review is the approval of research involving human subjects funded or regulated by the federal government or sponsors. Most of the research institution, professional organizations, and scholarly journals should apply the same requirements for conducting human intervention research. Although, the federal regulations used cited reference of IRBs for intervention of biomedical research, the institution may have chosen a different name for this committee for approval of various research projects. IRB constitute at least five members irrespective of gender that come from varied professions. At least one member whose primary concerns are in nonscientific areas and also one member who is not otherwise affiliated with the institution (Muirhead et al. 2012; McCormick 2008; Siegler et al. 1990). The reviewer should have toll experience and exposure in all of the areas of research being reviewed. At its discretion, an IRB may invite individual with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB diver-

![Fig. 12.6 Flow of document for review](image-url)
sity of background. An eagerly noted Sensitivity of community attitude, knowledge of institutional commitments, and reputations refrain from maintaining the highest standards which are applicable to human laws and standards of professional conduct and ethics in many-fold diversity of the legal aspects. The knowledge and experience with vulnerable population are necessary for review committee (Rawls 1999; Singh et al. 2013; Satyanarayana Rao 2008; Simon et al. 2000). If an IRB can review research projects that would involve vulnerable subjects, the IRB must consider the inclusion of an individual who has knowledge of human ethics and also got experience with these vulnerable subjects. The regulation may also require a voting right of IRB member who has relevant expertise. IRB may call experts to help with problematic reviews, but those persons may not vote on the disposition of the application. If an IRB member has conflict of interest, that member cannot be present for the review of that research project except to provide the IRB with information as requested and may not vote on that particular research study or intervention. Researchers should protect IRB guidelines and enable the rights and welfare of human subjects who participate in research, and understands and anticipates with ethical standards, regulatory requirement, and governing research activities with human subjects; IRB should intervene to address the issues and guide the institution properly, and inform research staff of the regulations governing research and the Institutional research policies. Ensure that all research activities have IRB approval and required by the institution before human subjects are involved. Implement the research activity as it was approved by the IRB. Obtain the informed consent of subjects before the subjects is involved in the research and document consent as approved by the IRB. Researcher should maintain written records of ethical clearance signed documents concerning about study population, methodology and objective of the research, and document consent as approved by the IRB and also comply with the IRB requirements, and every concerned institution shall be timely reporting of unanticipated problems involving risks to the human subjects or others including adverse events; the safety reports would be received from the sponsors or data safety and monitoring summary reports from the IRB to institution. So, we have to obtain the continuum development linkage to the IRB on scheduled data. The institution should make a provision for the secured retention of complete research records and all research materials so as to ensure that the confidentiality and security of all informations will be obtained from and about human subjects. The institution should verify the IRB approval, will be obtained from all participating institutions in collaborative activities with other institutions. For the information sake, the institution should notify the IRB guidelines in the public notice board for reviewing the guidelines and make use of IRB regularity for submission of new proposal and human intervention subjects in accordance with speculated regularities or guidelines.

12.9 Informed Consent

Definition—A process by which a subject voluntarily confirms his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of trail, trail that are relevant to the subject’s decisions to participate. It is the responsibility of an investigator to obtain from the prospective respondents, which can explain individual autonomy, ethics, and novelty of the research project and also inform consent must be readable and all research information are presented in local language. The objective, methodology, and outcome of the research should convey the patients or volunteers. The consent form should include title of the research project and main conditions that the participants are being asked to agree to it. Importantly they will need to agree to the completed consent form being checked by designated experts as part of ethical approval auditing process. During the study intervention, the researcher should take undertaking from the participants regarding confidentiality, publication process and report submission (Fig. 12.7).
The research participant should be aware of the nature of research and the probable consequences of the experiments or drug trial and then should make independent choice without the influence of the treating doctor, whether to take part in the research or not. When the research treats any community or group of persons as research participants, these principles of voluntariness and informed consent should apply to the community as a whole and also to each individual member who is the participant of the research or experiment. However, the principles of nonexploitation research participants should be remunerated for their involvement in the research or experiment. The participants should be made aware of all the risks involved irrespective of their social and economical conditions or educational levels attained. Each research protocol should include provisions of compensation for the human participants either through insurance cover or any other appropriate means to cover all foreseeable and hidden risks. Another intervention privacy and confidentiality, all data sets acquired for research purpose should be kept confidential to prevent disclosure of the identity of the involved participant and should not be disclosed without valid legal and/or scientific reasons. The principle investigator or researcher should conduct clinical experiments in fair, honest, impartial, and transparent manner after full disclosure of his or her interest in research (Simon et al. 2000; Thatte 2007). They should also retain the research data sets, subjects to the principle of privacy and confidentiality for minimum period of 5 years to be scrutinized by the appropriate legal and administrative authority, if necessary. Further, the princi-
ples of the maximization of the public interest and of distributive justice, the results of the research should be used for the benefit of all humans, especially the research participants themselves and/or the community from they are drawn and not only to those who are socially better off. Institutional agreement is required that all institutional agreements required to be made in respect of the research and its subsequent use or applications should be duly made in a transparent manner. Since the public domain is very important, we cannot deviate from our moral ethics, all the resulted part work done by the researcher should be made public through publications or other means. Even before publications, the detailed information of clinical trials should be made public before the start of recruitment via clinical trial registry system that allows them to access free online information. Principle of totality of responsibility explains that all those directly or indirectly connected with the research should take professional and moral responsibilities, for the due observance of all the principles, guidelines, or prescriptions laid down in respect of the research. Informed consent clearly explains the statement about the problems, benefits and economic feasibility of study participants, and also the explanation of purpose of research and the expected duration of the subject’s participation, inclusion with description of the procedure to be followed and identification of any procedures which are experimental, any reasonable foreseeable risks or discomforts to the subjects (World Medical Association 2008; Yamey and Roach 2001), a description of any benefits to the subjects or to others which may reasonably be expected from the research, trial treatment schedule and the probability for random assignment to each treatment, and a disclosure of appropriate alternative procedures or courses of treatment.

12.11 Discussion

In recent times, medical ethics has been greatly influenced by the development in human rights. Physicians frequently have dealt with various medical problems, e.g., organ transplantation, stem cell therapy, evidence-based medicine, clinical trial, drug adherence study of life-threatened, and lifelong diseases. However, these human ethical interventions are closely related to law, often to ethics is higher standards of behavior then does the law, and occasionally either require that physician or researcher disobey laws that demand unethical perspective and also violation of human rights. The basic ethical principles like A: Autonomy, B: Beneficence, J: Justice, and N: Nonbeneficence are closely associated with the dignity of human and respect for the patient or participants. An informed consent and confidentiality are basic to the physician–patient relationship and create positive atmosphere in the study site or threat area. However, the application of these principles in specific situation is problematic due to lack of cooperation from the patient care takers, lack of literacy and interest for participation in clinical and medical research. Since physicians, patients, their family members, and other healthcare professionals may disagree about what is the right way to act in a situation intervention of drug trail experiment, health care professionals were obtain undertaken from the participants and create a positive outcome of the trail, while trail also potentially pursuing the data collection without harm participants on the basis of ethical perspectives. Trail would be deviated from the normal ethics, such kind of trail is known as the double effect, e.g., the morphine in the dying patient eases pain and suffering while hastening the demise through suppression of the respiratory drive. During the study period well-being of human subject should take precedence over the interest of science and society, patient consent should be obtained in writing, physician use caution if participant in dependent relationship with the researcher, limit use of placebo and also facilities should be extended to the health benefits and to minimize the risk factors. So many drawbacks on medical ethics, for example, guidelines may be difficult to apply in new cases for several reasons, need to be interrupted in the context of case-to-case variation inherent, different priorities, and goals for care, distinguishing cases in ethically meaningful ways and also shortcoming of the existing guidelines.
12.12 Conclusion

The practice of medicine and conducting clinical research would be much easier if there were a fixed hierarchy of ethical guidelines. Since the ability to make prudent solution and decision could be taken in some specific situations, involving an understanding of how ethical guidelines are relevant for the benefits of patients and their well-being (a variety of situations and to the particular case at hand).

12.13 Future Line of Work

The discipline of science is to have an objective to spread the knowledge to the world; the objective of the research has been derived from many unfolded postulates that have been enriched with evidence, and the discovery of new horizon enhanced our world with useful technology. Since throughout the research process, analytics and modeling techniques are used to subject the sample size determination, screening of patients, development of algorithms, optimization of massive medical research data sets, and various methodological insight; the research is the incremental process between the research hypothesis and the ecosystem of advanced method of statistical intervention. However, many researchers focus to demonstrate real information in thought of mathematical and statistical form to fill the research gap on a full-blown basis. As such being the case, the researcher could not apply the perfect statistical analysis during compilation and final stage of research due to lack of statistical knowledge. In spite of this problem, the present book embedded various advanced statistical methods for the benefit of well-being of the researcher. In addition to that, the cited model helps to guide the researcher, and it should be concealed to obtain critical suggestions and statistical inputs from the professional statistician before induction of research. Thereby all the research interventions are associated with error components, hence the researcher should focus on the error component rather than nurturing the suitable appropriate statistical method for reduction of errors during analysis of data sets. On a broader sense, the analysis part will always be subject to the probable errors and negative predicted values. Although those same flawed humans who conduct and care about science ever refine the scientific processes to reduce errors and increase rigor. Much good has been done on this, and much good remains to be done ahead. The researchers’ lines of investigations and induction of research in any discipline of science because of innate interest, a deep curiosity, a desire for new findings, discovery, or a personal connection to the problem in the interest of frontier of advanced research. At this point, we conduct experiments, analyzing datum, and observing the research ecosystem and not just the aspects of science, and also represent personal interest and passions. Thus, when resulted findings provide something interesting whether simply intellectually stimulating or of profound practical importance, passion and excitement risk overriding the inherent fact. However, science has always designed new technology and discovery based on the mathematical and statistical derivation and also furnishes the antidotal information to the researcher to obtain research inputs from subject experts. As per the intellectual prosperity, the new technology and analytical standards will be necessary to increase our ability to detect some error components or research behaviors. In this aspect, new software and advanced statistical modeling techniques would be necessary for detecting the sample and population errors during interim analysis of clinical and medical research data sets. The present driven modeling technology cited in this book will support the researcher for development of new algorithms to identify and reduce the errors before submission of manuscript or final report of research projects. Cost–benefit analysis on the production of drug/vaccine and conducting the trials in the population and environmental conditions are important aspects to be considered for future research.
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