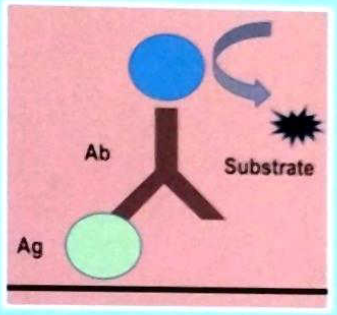
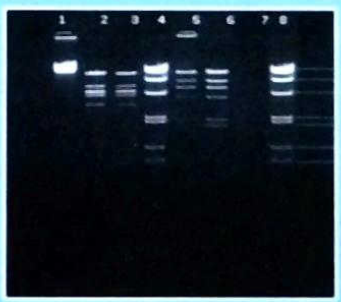
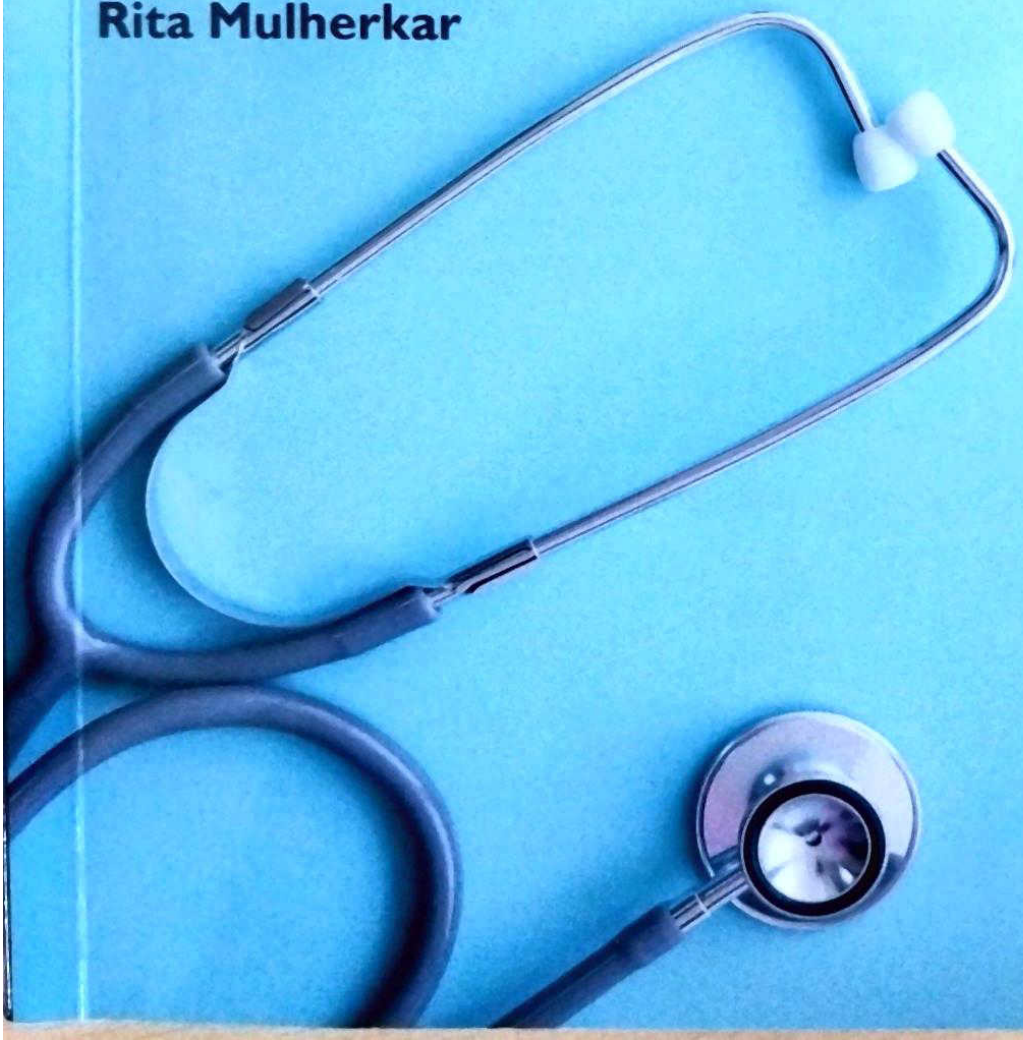
RESEARCH ORIENTED MEDICAL EDUCATION

THE ESSENTIALS

Editors
Madhav G. Deo
Renu Bharadwaj
Rita Mulherkar







With compliments of the Editors

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Madhav G. Deo, Renu Bharadwaj, Rita Mulherkar

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Requests for permission should be addressed to
deo.madhav@gmail.com, rmulherkar@gmail.com,
renu.bharadwaj@gmail.com

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4

Ethics in Biomedical & Health Research

Roli Mathur

1. Introduction

Rapid advances in the last few decades have added complexities to the understanding of ethical issues surrounding medical research. There is a need to raise awareness for better understanding. Biomedical and Health research needs to be done on priority. However, we need to ensure that research is conducted in a manner that safeguards and protects the research participants, builds their trust and overall it is responsive to the nation's needs. There should be no compromises on the scientific aspects to maintain the quality of research outputs. As biomedical research evolves, it also brings forward novel challenges with advancements and newer technologies impacting the need to revisit research ethic requirements.

Studies involving human participants are necessary to improve scientific knowledge and developments in health care. The primary objective of researching humans is to create new knowledge in disease prevention, diagnostics, therapeutics and larger public health goals. As new knowledge becomes available, we need to continually check the safety, efficiency, effectiveness and accessibility of existing regimens or interventions. The social and scientific value of biomedical and health research has to be central. When the need and expected benefits outweigh the risks and burdens of the study then research involving human participants becomes meaningful. The researcher must have adequate knowledge of the ethical, legal and regulatory norms of conducting research involving human participants. Every biomedical and Health research must be suitably aligned with the core ethical principles as per the ICMR National Ethical Guidelines [1].

2. Historical Perspective

Ethics, morality and values are the essential virtues that form the basis of biomedical health research ethics. Historically, one of the earliest mentions of the principles of ethics has been made in Charaka-Samhita as well as Sushrut-Samhita. These ancient Indian scriptures have discussed the moral obligations of medical professionals towards society, the need to have moral standards and to be a humanist [2]. In Western literature, a key concept of

the Hippocratic Oath is primarily to 'do no harm' [3]. Unfortunately, the world witnessed numerous inhumane crimes against humanity in the name of human welfare, such as around World War II when unethical and brutal experiments were carried out in many countries such as Germany, Japan and China on the prisoners of war without obtaining their consent.

Further exploitative research studies were conducted for over four decades such as the Tuskegee Syphilis study in which unaware persons were given false promises and not informed about the disease and its available treatment since they were being followed up to understand the course of the disease. They were denied the rightful treatment even after it became available. Following these unethical experiments, a series of guidelines, documents and codes of conduct were prepared and released from time to time by various international agencies and bodies. A few of these codes are the Nuremberg Code, Belmont Report and Declaration of Helsinki by the World Medical Association [4, 5, 6]. Further to this, other international agencies such as the World Health Organisation (WHO), Council of International Organisations of Medical Sciences (CIOMS), United Nations Educational, Scientific and Cultural Organisation (UNESCO), Nuffield Council and others have brought out guidelines for research in specific areas which provide direction on how the research should be undertaken. The International Council of Harmonization - Good Clinical Practice Guidelines (ICH-GCP) provide detailed harmonized standards for ethics committees, investigators and sponsors to conduct clinical trials involving drugs or devices in different countries [7].

These numerous documents, policies and guidelines have discussed the importance of having a framework for the ethical conduct of research to protect human rights, welfare and safety of the participants. They suggest the need for a prior review by an ethics committee comprised of independent members to undertake an unbiased ethics review before any research is conducted. These have further highlighted the need for obtaining informed consent to ensure that the participation is not coerced or forced but is completely voluntary, and the consent is provided by the participants after ensuring comprehension. Even though the fundamental principles remain the same, the ethical guidelines have evolved over the years as and when newer issues come to the fore with emerging technologies and their applications.

3. International and National Guidelines

Every nation should formulate its own ethics guidelines or regulatory framework based on its need and requirements and for the protection of its people. They may adopt the existing International guidance documents or develop their own National Guidelines according to their specific requirements. In India, the Indian Council of Medical Research (ICMR) has been at the forefront in setting up ethical standards needed for biomedical research. In 1980, ICMR prepared the first ethical Guidelines called the Policy Statement on Ethical Considerations involved in Research on Human Subjects. The ICMR has set up a Central Ethics Committee on Human Research (ICMR-CECHR), which functions as the National Ethics Committee to guide its research and develop a National policy and guidelines around emerging ethical issues. Over a period of time, the ICMR ethical guidelines were thoroughly

revised to include more details and were published in the year 2000 and 2006. The latest guidelines, the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, were prepared and released in 2017. During the Covid-19 pandemic the ICMR came up with additional guidelines for the ethics committees to review research [1, 8]. It prepared a handbook on the National Ethical Guidelines, which is a useful brief guidance relevant to students and Researchers. Further, the Standard Operating Procedures (SOPs) for Emergency reviews by the Ethics Committees, which are not only useful but facilitated research reviews during the pandemic, were prepared. In addition, ICMR has come up with a number of other guidelines and policies, such as Research Integrity and Publication Ethics which discusses in more detail Responsible Conduct of research [9]. The ICMR has also prepared other reports such as Definitions pertaining to End of Life Care and Do Not Attempt Resuscitation Consensus Guidelines, which gives insight into the end-of-life care issues [10]. It has also developed templates for Common Forms to make submissions to ethics committees which are useful in harmonizing the submission to EC and ensuring their completeness [11]. The ICMR is working closely with the Department of Health Research (DHR) to set up a National Ethics Committee Registry for Biomedical and Health Research on the Naitik Portal [12]. After years of efforts, The New Drugs and Clinical Trial Rules, 2019, have made it mandatory for all to follow the ICMR National Ethical Guidelines for any biomedical and health research in India and to register every Ethics Committee with the DHR [13].

4. General Principles

No where in the world can research be conducted on humans, their data or biological material without obtaining ethical clearance. Both national and international guidelines have highlighted the importance of the principles that need to be followed to ensure ethical standards. These are Autonomy, Beneficence & Non-Maleficence and Justice. They are discussed below:

i. **Autonomy** translates into 'Respect' for participants who become part of the research. They must be provided adequate information about the research and given ample time to think and decide about participation. Their decisions should be respected and their participation must always be voluntary and never forced. Special protection has to be given to vulnerable persons who are unable to safeguard their rights.
ii. **Beneficence and Non-Maleficence:** Research has to always be beneficial and never harmful. All human research should follow the principle 'maximize benefits and minimize risk'. Research must have a favourable benefit-risk ratio to be ethically acceptable and steps to minimise the risks should be planned.
iii. **Justice:** This principle deals with the concept of fairness. The researcher designing the research should consider what is just in terms of recruitment of participants and choice of location to conduct the study. There should be no selection bias, stigma or discrimination towards any participant or community. Results or outcomes of research should be shared with the participants.

Autonomy:

Research needs to protect the rights of individuals and respect their preferences. Furthermore, one of the fundamental principles of research ethics is protection of individual autonomy. In order to impart due respect, the ICMR Guidelines no longer refer to persons who join the study as 'Subjects' but have switched to using the term 'Participants', indicating how patients or persons who join the research are equal partners and deserve due respect [1]. The principle of autonomy further necessitates the need for informed consent to respect the individual's rights and facilitate autonomous decision making without any coercion or influence. All research on humans should reflect the respect and concerns given for human rights and welfare of individual participants. The responsibility of protecting research participants rests with all stakeholders involved in the research enterprise, such as researchers, EC members, sponsors and other regulatory bodies. It encourages autonomous decision-making.

Informed Consent

The informed consent process facilitates autonomous decision-making thereby protecting the autonomy of the individual participant. It further requires provisions to be in place to ensure that the research study participants have been provided with relevant information about the nature of research, procedures, outcomes, possible adverse events, etc., and that they have comprehended the same. The purpose of the informed consent form is to disclose and discuss relevant details of the research with the participants. The informed consent process is not only about disclosing relevant information but also about comprehension and understanding of the participants. The researcher must make a meaningful effort to assess the participants' understanding of the research process and appropriately communicate their role as participants.

The informed consent document is signed and obtained from potential research participants by explaining all the relevant information regarding the study. It has to be obtained without any kind of influence or pressure to allow individuals to make informed decisions. It is the responsibility of all stakeholders to ensure that there is voluntariness in the consenting process. When a potential research participant gives consent, he/she acknowledges their participation in a designated role in the study. The informed consent document should especially emphasize that the participation is completely voluntary and that the participants are authorized to withdraw from the study without any negative effects or consequences.

In some situations, the potential participants may not be able to give fully informed consent as in the case of minors or persons with some types of disabilities limiting their decision making. In certain scenarios, researchers may be required to take consent from the Legally Authorized/Acceptable Representatives and prior approval from EC is required for the same. In the case of children, it is important to respect their autonomy and seek assent while the consent may be obtained from the parents or LAR before enrolment. In situations

where the potential participant cannot give signatures or thump impression in the informed consent form, the researcher can obtain verbal or oral consent in the presence of an impartial witness with prior permission from the EC [1].

An Informed Consent Form must be prepared in a simple language and manner that a person can easily understand the same. It should have basic elements such as to state that it is a research, mention briefly the purpose of study, explain the methods and procedures involved, inform about the risks and benefits, how confidentiality would be maintained, contact information, provisions for compensation, the voluntary nature of research and possibility to withdraw at any time. It is also important to understand that informed consent process is not a one-time activity of signing a sheet of paper, but a process that is initiated before the research begins and it continues while the research is ongoing and then after the study is completed. There is an ethical responsibility to communicate the outcomes and findings and share the benefits with the participants as far as possible.

Privacy and Confidentiality

Research has to be conducted with sensitivity respecting the private and confidential information of the participants and their family members. An individual's health information is sensitive data and it has to be kept confidential. It is the responsibility of the researchers to safeguard the information from any unauthorized access, disclosure, loss or theft. There should be clarity on how the information will be collected, stored and shared. There should be safeguards to protect the information and ways to protect from any unauthorized access. The participant has a right to determine the extent of their personal information obtained through the study and control the use and manipulation of their sensitive information.

The confidentiality clauses may protect the participant from harm and this responsibility is vested with the researcher/sponsors/research team and all other relevant stakeholders involved in the study. The limitation to ensure fail-proof confidentiality must be explained and also who would be able to access their information or how it will be published must be informed. Research on sensitive topics needs care since any breach may lead to stigmatization or discrimination thereby harming the participants.

Similarly, any identifiable data from a participant cannot be published without prior informed consent from the participant. Biological samples and clinical records should be collected and stored with care. Institutions involved in bio-banking or storing the records and data must have adequate infrastructure to protect against a breach. They should also have defined policies regarding who can access the data/information and how. Research participants' data may be coded or anonymized to maintain privacy and confidentiality. Further, if any identifying information is collected which is required to be shared or published or if leftover samples are stored for future research purposes or sent to bio-banks then specific informed consent would be required [1, 8].

BENEFICENCE & NON-MALEFICENCE

The term Beneficence highlights the need and importance of doing good. In terms of research, it translates to qualities of kindness, helpfulness and humanity, and in general, refers to promoting the good of others to further their important and legitimate interests, often by preventing or removing possible harm. Beneficence is closely aligned with the principle of Non-maleficence, which stipulates the obligation of "first of all, do no harm". The principle of beneficence requires the researchers to use scientific knowledge and protect the participants from harm. On the other hand, the term Non-maleficence is also an inseparable pillar of ethics reflecting upon the duty to not allow any harm to the research participants due to neglect or oversight. Researchers must try to do good and refrain from providing ineffective treatments or acting with malice towards the participants [1].

BENEFIT-RISK ASSESSMENT

Before recruiting participants, a favourable benefit-risk assessment should be ascertained to understand the risks, benefits and the social and scientific value of the research. Primarily every research must have a social and scientific value. The benefits, which could be direct or indirect, must justify the risks, inconveniences, discomforts or harms that may be caused due to participation in the study. These benefits need to be identified and could be direct health benefits such as psychosocial support, counseling or indirect benefits such as care of allied diseases, referrals and others. Any monetary payments or reimbursements are not taken in terms of benefits. On the other hand, the risks or harm could not only be physical related to intervention but also social or psychological, monetary or others. Every study would have inherent risks and efforts must be made to see how these risks or discomforts can be minimized or reduced. Risks can be categorized into less than minimal, minimal, low or high. This categorization is important as it helps to understand the category of risk and if the benefits are enough to cover these risks [1].

The ethical justification for exposing people to risk is the potential individual and community benefits derived from the study. It also helps in adding new knowledge to the field of medicine for the protection and promotion of people's health. The risk-benefit ratio is not a mathematical entity that can be expressed in numbers or as a formula. Rather, it is a conscious judgment and careful assessment of the risks involved and expected benefits based on the available evidence. The researcher has to provide a credible interpretation of available evidence to support their judgment that the study has a positive risk-benefit ratio before submitting the study to the Ethics Committee for approval. The Ethics Committee members further evaluate the benefit-risk ratio and ensure that the risk involved is balanced by the individual benefit from the study. The measures for minimizing the risk for the participants must be balanced with the competing interest of public benefit, scientific value and fair selection. There should be due provisions for addressing the health needs of the participants during the period of research. The risk-benefit assessment is also not a one-time activity but needs to continue when the research is ongoing as there may be

altered risks as the study progresses or as new information becomes available or in light of participant's concerns or media reports. All relevant stakeholders including the researchers, sponsors, EC members must rigorously scrutinize the research protocol and look for ways and opportunities to minimize the risk for the participants.

Payments for Participation and Compensation for Research related injury

Payments for participation refer to the reimbursements or other payments in cash or kind to cover the additional research-related costs incurred by the research participants. Offering large monetary rewards or big incentives may pressurise prospective participants to agree to be part of the study. These are called undue inducements or coercion. On the one hand, there should be some provision to cover the costs related to reimbursements wherein these amounts should be reasonable and justifiable and preferably be in kind rather than in cash. Accordingly, researchers must make needful provisions for paying participants for their losses in wages or the cost incurred for transportation or other expenses incurred due to participation in the study or provide them with food during the time spent at the research facility. Any kind of extra payments in cash or kind or as gifts or incentives has to be declared to the Ethics Committees, which would review the same in line with the risk and inconvenience and cost of participation involved to ascertain if these would be ethically appropriate or not. The Ethics Committee needs to further ensure that the study has appropriate budgets and that the amounts to be paid for reimbursement of expenses are reasonable and will not become an undue inducement for participation [1].

Payment of Compensation for any research-related injury is another area which is not well understood or implemented. The ethical requirements for all types of research requires that the research participants be duly protected and institutions involved in the research must build corpus funds or plan insurance schemes to cover the costs related to medical management as well as payment for compensation of research-related injury. The research study must also plan to have dedicated budgets or insurance policies to pay for any medical management that needs to be provided to a research participant if he/she suffers from an injury. Compensation must be paid once the causality is determined and it is found that the injury is related to research. Often it is seen that only pharma-sponsored clinical trials have built-in provisions to pay for medical management and compensation whereas other academic studies, student thesis and investigator-initiated research studies do not have any provisions to pay compensation. Details of provisions made in the study for payment for participation, medical management and compensation for research-related injury have to be submitted to the Ethics Committee for review and approval before the initiation of the study [1, 13].

Conflict of Interest

Conflict of Interest (COI) is said to arise when a secondary judgment unduly influences a primary professional judgment. The primary interest should be research objectives; however, various secondary interests exist such as the need for promotions, fame, awards,

publications, monetary incentives, friendships, relationships, power relationships, hierarchy and others that may unduly influence decisions. An independent observer may reasonably believe that the professional judgement is biased in the presence of Conflict of Interest. This COI can be at any level such as a researcher, member of the Ethics Committee or an institutional authority which may pressurize approvals. The existence of COI damages the trust invested in the relationship and affects the research's integrity.

Conflicts of Interest are very common and therefore having a COI does not imply that there is wrong-doing or improper motivation, but it is always imperative to identify the COI, declare it and manage it accordingly. Disclosure is the golden rule and the researcher must disclose their COI that may affect the research, to the EC in a timely manner. The Ethics Committee would deliberate and suggest useful steps to overcome the same. If the COI exists within the EC, the member must leave the room and not be part of decision making, and due recording of this has to be in the minutes. Institutions and organizations must focus on improving awareness about COI by promoting training and education for the students and Researchers. Institutions engaged in research should have a policy on managing COI and this policy must be shared with all the relevant stakeholders.

COLLABORATION

Research is a multidisciplinary enterprise and often requires collaboration at departmental, institutional, regional, National or International levels. This collaboration should be built on the principles of equal partnership, fair agreements and transparent processes to ensure that the fruits of research can be harvested well. Collaborations can have an exploitative potential if the partnerships are on unequal platforms and can cause unnecessary suffering to participants, violate their rights and cause agony among researchers. Collaborative research involving samples or data, sharing, analysis and publications must follow transparent procedures outlined in the research protocols and all stakeholders need to be responsible for the outcomes.

Whenever there is sharing of information of participants, samples, clinical data, genomic samples or epidemiological data, there should be clarity on the ownership and custodianship as well as long-term storage. Appropriate Memorandum of Understanding (MoU) or Material Transfer Agreements (MTA), need to be signed. All involved stakeholders need to be accountable and register the research on a public platform such as the Clinical Trial Registry of India (CTRI) [14]. Studies conducted in international collaboration must ensure that the rules of all partnering countries are applicable, respected and followed.

JUSTICE

Equitable Distribution

Justice implies that the burdens and benefits of the research are fairly distributed, and there is equitable distribution ensuring that there is no exploitation of participants at any point of

the study. The researchers should not disproportionately focus only on the health needs of a limited class of people, but instead they should strive to address the diverse health care needs of the people across different social and cultural classes or groups. No particular person or group should be stigmatised, targeted or discriminated against. There should be fair processes to ensure that the right people receive the required care and share of benefits.

Protection of the Vulnerable

Special care must be given to ensure that the socially disadvantaged and marginalized populations are not over-represented due to ease of recruitment or by offering them undue inducements. Vulnerable persons need special care, support or protection because of age, disability or risk of abuse or neglect. They are often not in a position to protect their rights and interests and therefore, the Researchers must take due care and protect them from discrimination. It is unjust to selectively recruit those who may be easy targets or who may not have access to research benefits. In the past, groups considered vulnerable were excluded from the studies to protect their rights. As a consequence, the information on diagnosis, prevention and treatment of diseases which affect the particular group was limited. This created serious injustice to the disadvantaged population. The ICMR National Ethical Guidelines state that it is important to recruit persons who are vulnerable if the study would answer their health needs and if there are additional safeguards in place to protect their safety and well-being [1].

New knowledge and information about the disease would benefit society as a whole. It is unfair to intentionally deprive a specific group from the burden and benefit of the Research. Often it is not easy to identify who can be vulnerable. Certain groups of people such as children or pregnant women or tribals or refugees etc can be easily classified. However, certain others are socially or economically deprived or those who are made vulnerable due to the situation or hierarchy such as being a student or subordinate cannot be classified. It is important to adequately protect them when they are made part of the research and the researchers have the responsibility to identify these vulnerabilities and take care to avoid any suffering or hardship.

The Ethics Committee reviews a study and ensures that if the study involves any person or group of people who may be vulnerable, the protocol has built-in provisions to take care of their rights and safety. They may make suggestions for safety measures and the appropriate documentation of informed consent is important. Informed consent in such cases also needs more care and may be done in the presence of the legally authorised/ acceptable representative or the EC may suggest the need for an impartial witness depending on the type of research and the participant group involved.

Community Engagement

Often while planning research, the investigator's main concerns are related to their research objectives and not much focus is given on how to engage with communities that will be

involved in the research or how the research should be planned in the best interest of the communities that would be involved. For meaningful research, it is important to keep the interest of the involved participants or the communities on board and tailor the research as per the needs and requirements. There should be plans for good communication to understand the needs and requirements and build relations and trust with the communities involved.

The research should cater to the needs of the groups who participate and the benefits of the research should be translated back to them. For this to happen, meaningful community engagement is crucial. Researchers and the study teams must plan methods to understand the needs and engage with the communities to improve the study design, plan its conduct and implementation. A useful suggestion is to make a community representative a part of the study team if the nature of the research permits so. Similarly, when the Ethics Committees conducts their ethics review, they can invite community representatives as special invitees to better understand their perspectives. This would help in ensuring that the study takes care of the ethical and societal aspects and will be better tailored to find answers to the group's health needs. For certain types of research studies, the Ethics Committee may suggest the formation of Community Advisory Boards which can strengthen the understanding of the community perspective and help in better engagement for meaningful research outcomes [1].

Benefit Sharing & Return of Research Results

All stakeholders involved in a research enterprise have a moral responsibility to ensure that the benefits of the research finally reach the participants. Normally researchers feel that the research ends with a publication. Unfortunately this is not true. The outcomes must go back to the people or there must be channels to ensure public health benefits. In both, clinical trials as well as biomedical and health research, efforts have to be made to have provisions for post-research access of products/benefits to the participants. This requires equal partnerships, ways of encouraging participation and fair distribution of the burden and benefit of the biomedical research.

The research protocol must be designed with careful consideration given to the protection of disadvantaged populations who cannot protect the patient's rights. Upon completion of the research, it is the moral responsibility to ensure its translation to health benefits of the persons or their communities who participated. Researchers must have a priori agreements and plans to provide access to products developed in the research. Similarly, where studies lead to knowledge generation, efforts must be made to communicate the research findings so that the participants are not left in a lurch and unknowing of what happened to the sample or data collected from them. In the event of commercialization of research products or patents or royalties that may be received, it is important to share the same with the people who have contributed their samples or data for the research. These benefits may go to actual individuals who were part of the research or also to the communities or population groups who were involved. Often these benefits may not be direct or monetary but could also be in terms of building infrastructure or providing counseling or better medical care or health

care facilities or advocacy and education about health practices, and so on. The idea is to provide benefit in any form to those who have contributed to the research [1].

5. Ethics Committees

An Ethics Committee is an independent group of people with multidisciplinary backgrounds who are responsible for undertaking an ethics review of biomedical and health research before it is initiated to safeguard the rights, safety and well-being of participants involved in the research. They must be competent and trained to review the research and must be independent in their decision-making to ensure robust ethical review processes [1].

Composition

The Ethics Committee is composed of a multidisciplinary group of experts with the primary objective of protecting the dignity, rights, safety and well-being of the participants. The members are drawn from a variety of fields to have a wider perspective that will help protect the interests of the research participants. There are clinicians, basic medical scientists, legal experts, social scientists, ethicists, theologians, philosophers and laypersons from the community whose role is critical as they represent the interest of society. The committee can further co-opt or invite special invitees such as subject experts, community representatives, patient representatives and others who can provide firsthand information to tailor the protocol and informed consent process to suit the best interest of people at large.

Functions

Every research study has to be submitted to an Ethics Committee before it is initiated. The committee reviews the research protocols and ensures that the study is conducted in a manner that it safeguards the rights, safety and well-being of research participants. The Ethics Committee must consider feasible methods of risk reduction, maximize benefits and protect vulnerable persons such as children, pregnant women, the elderly etc., who may be recruited into the study. The Ethics Committee reviews both science and ethics since a study with bad science can never be ethical. Depending on the risk involved, the Ethics Committee decides on the type of review required for the study. The introduction of innovative methods of informed consent, data collection, participant recruitment, etc., is under the purview of the Ethics Committee and prior approval is necessary before its implementation.

The approval of the Ethics Committee is not a one-time process it is also required to monitor the research to ensure that it is being conducted in compliance with the approved protocols. The EC may monitor site visits whenever required to ensure that the research team is carrying out the research as per plan and that the participants are duly safeguarded. Ethics Committee reviews possible modalities for reducing study-related risks and their management. It ensures that there is provision for the management of research-related

injuries and measures are taken for risk reduction. It also ensures that the rights, dignity and well-being of the participants are protected throughout the study.

Ethics Committee Considerations

The Ethics Committee looks at all aspects of the research study. They look at its science and social value and how it will be implemented on the ground. They review the selection of participants at the site, facilities, study team qualifications and infrastructure available to support the research. They also look at study related risks to the participants and the possible benefits. The Ethics Committee reviews all the measures taken to protect participant confidentiality, privacy of individuals and safety and security of the stored research data. Inappropriate disclosures or use of data may bring unnecessary hardships to participants. All stakeholders of the study have a moral obligation to uphold the privacy of each participant. In case of any breach or loss of data, the researcher has to inform the Ethics Committee which decides the further course of action depending on the sensitivity of data and potential implications due to the breach.

The Ethics Committee reviews how data is being stored, how it will be used in future and who can access it. Research needs to be conducted by duly qualified people with necessary training and expertise. Ethics Committee requires a declaration of conflicts of interest by researchers and EC members whether financial, academic or personal, and suggest suitable mechanisms for managing the same. Ethics Committee members have also to declare their conflict of interest. They also look at the payments involved in the study and if adequate arrangements are in place to pay compensation in case of research-related injury. The Ethics Committee reviews the process of taking informed consent and ensures the voluntariness of participants. They are also involved in monitoring the implementation of the study on the ground and are wary of any societal concerns, if any. All these functions of the committee need to be supported by an EC secretariat appointed by the institution with adequate staff and infrastructure.

Ethics Committee Registration and Quality Assurance

Ethics Committees have to be competent and timely in the process of review. They must be abreast with national and international guidelines as well as developments that relate to biomedical and health research. Recently, it has become mandatory for the Ethics Committees to be registered with central agencies. Ethics Committees reviewing biomedical and health research must register on the Naitik Portal with the Department of Health Research, Ministry of Health and Family Welfare, and the Ethics Committees reviewing clinical trials need to be registered on the SUGAM portal with the Central Drugs Standards and Control Organisation, under Department of Health, Ministry of Health and Family Welfare. This structure has been created to ensure the Ethics Committees' accountability and to make sure that they have appropriate composition and are functioning as per the national guidelines and regulations. This also helps to ensure that they undertake monitoring of research and

thereby safeguard the rights, safety and well-being of research participants. Further to the mandatory registration, provisions are available for participation in Quality Assurance Programs such as by the National Accreditation Board of Hospitals (NABH) to receive accreditation [15]. National and international agencies benchmark the Ethics Committees' performance against set standards to grant them accreditation. This helps to improve quality and be recognised to follow the best ethical practices.

6. Conclusion

Ethical considerations have to be central in the conduct of any biomedical or health research. There is a need to ensure that research is sensitive, more meaningful and tailored to answer the needs of the people and is carried out in a manner that respects their rights and safety. The research needs to work towards uplifting the health and prosperity of the participant as well as the community at large. These considerations help protect the participant's rights and well-being and protect them from unnecessary hardships. For every research, there has to be a mechanism for time-to-time monitoring of the participants' safety and well-being, especially those who are most vulnerable.

Institutions that engage in biomedical research need to make facilitatory provisions to support the ethical aspects of research. Ethical safeguards are required from inception to conduct of research, its actual implementation in the field and also in the follow-up and reporting of Research results, publications and finally in translating the findings for the public good. The participants and care for their perspectives and rights need to be safeguarded at every step. Research ethics is an ever-evolving vibrant and dynamic subject and requires time-to-time updating of guidelines brought out by various agencies. Ethical guidelines help to provide a framework to preserve the integrity of science and safety of participants and must be followed in letter and spirit.

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Creative minds are evenly distributed irrespective of caste, creed or geography. However, research, the mother of innovations, is highly neglected, especially in the developing nations, where young minds are often knowledge-starved and hardly exposed to current research culture. The ROME (Research Oriented Medical Education), is a mobile, short duration, in-study program of mobile research workshops on advanced medical and biomedical topics, hosted in medical colleges all over India, developed by the Moving Academy of Medicine and Biomedicine, Pune, India. The topics covered are clinically oriented such as study designs, biostatistics, ethics and application of information technology in medical research, as well as commonly used immunology, protein and nucleic acid technologies. The book, which is based on ROME, is aimed at promoting research culture in young creative minds.

Dr. Madhav G. Deo. MD, PhD, FNA. FASc, FNASc, FAMS
President, Moving Academy of Medicine and Biomedicine, Pune, India
Director, Cancer Research Institute, Tata Memorial Center, Mumbai (Retired)
Professor of Pathology (Past), All India Institute of Medical Sciences, New Delhi, India

Dr. Renu Bharadwaj MD
Consultant Microbiologist; Professor & Head Department of Microbiology (Retired); B. J. Medical College, Pune, India; Past President Indian Association of Medical Microbiology; Section Editor International Journal of Antimicrobial Agents; Editorial Board Member BMC Infectious Disease; Editorial Board Member Indian Journal of Medical Microbiology

Dr. Rita Mulherkar PhD, FNASc.
Professor; Cancer Molecular Biologist (Retired), Cancer Research Institute, Tata Memorial Centre, Mumbai, India; pioneering work in gene therapy of oral cancer; Editorial Board Member Human Gene Therapy

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