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REVIEW ARTICLE

Ethical Considerations in Research

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ABSTRACT
Modern research is influenced significantly by ethical and legal issues concerning the subject and the researcher. This review tries to enlist the various ethical guidelines and regulations issued by various international and Indian committees. Researchers should note the major regional differences in an international guidelines and legislation. Since the regulations differ from region to international, specific ethical guidance should be acquired from the local Ethics Review Committees. Respect for participant's preference and choice should always be prioritised. Full consent from the participants needs to be obtained prior to the study. Research ethics is exactly concerned in the analysis of ethical issues that are raised when people (or even animals) are included as participants in research.
Key words: *Ethics, confidentiality, informed consent, legal issues*

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INTRODUCTION

Ethics deals with ideology behind the moral principles of right and wrong. They form the principles that guide decision making and aid in reconciling when there are conflicting values. Most often, it is not an absolute concept, as it may vary depending upon the individual, time or place and at times be actually in competition with each other.

Ethics plays a vital role through all stages from inception to completion of research and finally publication of the findings. Initially, ethics governs selection of research question that are pertinent to addressing the pressing health concerns, prioritizing certain topics in comparison to others. Secondly, it governs the conduction of the research process with reference to design of the study to answer the research question, methods of obtaining consent, statistical methods used and interpreting the results. Thirdly, ethical considerations should be adhered to in publication of the research findings. And lastly, ethics are essential in resolving conflicts of interest and addressing funding obtained for the research. [1-3]

POLICIES AND CODES FOR RESEARCH ETHICS

Different governmental agencies, professional bodies and education & research universities have policies providing guidelines for conducting research. The most common ones are listed below;

- Economic and Social Research Council. UK – Guidelines
  It states every research should be designed, reviewed and undertaken to ensure integrity and quality. Staff involved and subjects included must be completely informed regarding the purpose, methods, possible uses and outcomes of research particularly of any risks involved. Anonymity and confidentiality should be maintained. Harm to participants should be avoided at all costs. Conflicts of interests should be explicit.
- Ethical Principles in Social Sciences. – These guidelines include
  i. Voluntary participation – Ensuring informed consent is taken from all participants.

They should consent to revealing information. Any observation taken in public situations is implied to have agreed, provided the participants are informed regarding the same.

ii. Non-maleficence – Is to minimize any physical or emotional harm to participants of research. Legitimizing risks is possible when outcome of the research balances short term risks over a long-term gain.
iii. PAC – includes Privacy, Anonymity and Confidentiality
iv. Beneficence – is to maximize benefit and promote well-being of subjects.
v. Autonomy – ability to make their own decisions.
vi. Integrity – In carrying out all the research processes.

- Belmont Report – was formulated by the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. It includes three primary ethical principles.
  i. Respect for individuals; comprises of two components first that people are entitled their own preferences and the second, not everyone is capable of self-determination and require protection. It requires subjects to be respected for their choices and participate voluntarily. Not complying by this would mean denying freedom to act based on individual judgements or holding back information that was essential to make the decision. Respect for incapacitated and those unable to mature decisions implies protecting them against harm based on the risk and benefit of the outcome.
  ii. Beneficence; states two complementary set of rules, firstly to bring no harm on those involved and next to maximize the positive outcomes while reducing the risks. Steps to secure the well-being of participants dates back to the Hippocratic oath. With reference to research, it implicates that risking even one individual's well-being for the benefit of many others should be avoided. Researchers have an obligation to avoid, prevent harm to participants. Harm could be in the form of physical, emotional, social or financial. All precautions should be taken to minimize all types of harm and discomfort, even those that might be temporary.

     Right to protection from exploitation entails safeguarding the participants from any risks involved. Study subjects should be assured that information provided and their inclusion into the project will not in any way possible be used against them. Hence to ensure this requires not only recording physical data but also data pertaining to patient experience.
  iii. Justice; It requires to consider if certain specific divisions of people are included as study subjects, such as those belonging to socially disadvantaged or particular race or ethnic backgrounds. It pertains to who is entitled to benefits or who is to bear the risks with respect to "fair distribution" and "who is worthy of it". It is articulated through two concepts; right to fair treatment and right to privacy.

     The first concept deals with equitable distribution of benefits and burdens of research. Research requirements should dictate the selection of subjects rather than easy access usually associated with compromised and vulnerable groups. It includes not doling out prejudicial treatment to those who declined to be included in the study. It also entails showing sensitivity regarding their cultures, beliefs, habits and lifestyles.

     The latter concept deals with confidentiality regarding the data collected during the study. All means to minimize intrusion into participant's privacy should be taken and only data pertinent to the study should be collected.

     Justice is breached when benefit is denied to those entitled to it or risk is imposed unjustifiably. Exploitation of unwilling but disadvantaged population group such as prisoners, e.g. Studies conducted on Nazi prisoners in 1940s would be considered as gross injustice. More recently it also means convey those benefits from research conducted through public funds should not be available to only those who can afford them. [3-5]

Apart from the above-mentioned guidelines, the common ethical principles of research can be summarised as; [6,7]

1. Honesty: data should not be fabricated, misrepresented or falsified. All components of research such as methods, procedures, data and results should be presented scrupulously without tampering or manipulation.
2. Objectivity: efforts to minimize bias and errors in all aspects of research should be done starting from design of the study, selection of participants, analysis and interpretation of data, inclusion of other members into the research team etc.
3. Integrity: Conducting the research with sincerity and consistency; and fulfilling promises assures integrity.

4. Conscientiousness: Maintaining records diligently, avoiding careless errors and negligence through proper supervision of the researchers.
5. Openness: Being open to improvements through new ideas and criticism. Providing access to resources, tools, data and results would ensure availability and access.
6. Respect for intellectual property: Refers to avoiding plagiarism, giving due credit and not using unpublished data without permission. Authorship should be provided only base on contributions to the research paper rather than official seniority. Reviewers for manuscripts or grants should maintain anonymity and confidentiality. They should also refrain from using unpublished data.
7. Responsible publication: Avoiding publishing duplicate data. Publishing should be done in order to contribute to vast scientific knowledge or as significant contribution to new ideology. Publishing just to advance one's own career would be considered as wasteful publication.
8. Responsible mentoring: Encourage decision making while providing necessary guidance and advice contributing to welfare of trainees or students. The relationship should diligently comply with the Ethical Code.
9. Respect for colleagues: Treating professional colleagues and team members with fairness and respect. Creating an environment that is conducive for advancement of knowledge and experience for everyone involved.
10. Non-discrimination: No prejudicial treatment based on race, sex, religion or ethnicity or any other factors that does not influence integrity or scientific proficiency.
11. Competence: Commitment to advancing and maintaining knowledge and expertise through consistent learning and continued education.
12. Social Responsibility: Allegiance to target societal harms and promote good in the society through research.
13. Legality: Abide by institutional or governmental policies that are present to safeguard rightful research.
14. Human subject's protection: Respect for human life, dignity, autonomy and privacy while conducting research. Safe guarding against risks and increasing benefits.
15. Animal care: Carrying out responsible research on animal and avoid unnecessary harm and ill designed studies.

INDIAN SCENARIO:

In February 1980, the Indian Council of Medical Research (ICMR) put forth first ever official guidelines for setting up ethical committees in research and medical establishments by announcing 'Policy statement on Ethical Considerations involved in Research on Human Subjects'. Later in 2000, ICMR published 'Ethical Guidelines for Biomedical Research on Human Subjects' which was later revised in 2006. It is mandatory for very research conducted in India to follow these guidelines that explained through three basic principles which are justice, beneficence and respect for individuals, that is elaborated through 12 principles which are as follows; [8-11]

1. Principle of essentiality
   Research should be undertaken with the sole purpose of advancing scientific knowledge and advantage of human race while safe guarding ecological and environmental concerns of the planet.
2. Voluntary enrolment and informed consent, including community agreement
   Participation in research should be based on individual preference that is the result of proper explanation of the research process, risks involved and the beneficial outcomes by the research team to the subjects of the study. The participant can withdraw at any stage of the trial irrespective of the any earlier obligation.
   In community-based trials, the decision to participate should be taken by the entire community as well as its individual member.
3. Avoiding exploitation.
   Participants should be selected such that benefits and harms are distributed among them without any prejudice or discrimination. Remuneration for the participants should be provided irrespective of their literacy levels or socio-economic status. Compensation by providing remedies for any unseen harms brought about by research should also be made available.
4. Principle of confidentiality and privacy.
   Unless required legally, data collected and identity of the participants should be kept confidential to prevent discrimination or stigma based on their participation in the trial.
5. Principle of professional competence.

Research should be undertaken in ethical and impartial way by well trained professional and competent researchers with integrity.

6. Principles of risk minimization and precaution.
   Ethical professional review should be conducted at every stage of research from its inception till publication, the study subjects or the community is at minimum risk and safeguarded from any adverse effects.
7. Principle of transparency and accountability.
   The research should be undertaken with complete transparency and honesty. Disclosure regarding conflict of interest is mandatory. However, true and complete records should be made available after the research is completed for administrative or legal scrutiny.
8. Distributive justice and focus on maximizing public interest.
   The outcome of the research should not be restricted to the affluent but be made accessible to all especially, the participants and their community.
9. Principle of institutional agreements.
   Institutional arrangements should be made in a transparent manner to ensure data, materials and reports associated with the research are archived and stored appropriately.
10. Principle of public domain
    Information regarding the trials should be made available even before completion of the trial by uploading the details on clinical registry such as www.ctri.in ; www.clinicaltrials.gov/ etc. The results once published after the completion of research should also made accessible based of the rights of the researcher.
11. Principle of assuming complete responsibility
    All members of the research team should assume responsibility for conducting the trial by observance of necessary guidelines and principles. This includes companies funding or sponsoring research and institutions under which research was conducted.
12. Principle of compliance
    All the guidelines, directives and norms hence stated should be complied with diligently by all members of the team while conducting research.

INSTITUTIONAL REVIEW BOARD (IRB)

It is a committee that ensures carrying out ethical research in the concerned institution. Hence, it is also known as 'Institutional Ethical Committee' (IEC). Apart from reviewing before start the study the IRB is also responsible for regular monitoring of the project through all its phases. Its major responsibility is to review project proposals objectively for adherence to ethical guidelines. In institutions that lack a scientific committee, ethical committee has the added obligation of reviewing the technical aspect of conducting the research. Hence the functions of an IRB can be summarised as;

- To safe guard the rights, well-being and dignity of study subjects.
- To make sure ethical guidelines and international standard scientific protocol are followed and integrated with community beliefs and customs.
- To educate and familiarize research and scientific community with the health needs of the population. [8]

IEC is multisectoral and multidisciplinary that comprises of eight to twelve members from varied fields, headed by a chairman who is not from the institution is a mix of scientific and medical professionals comprising of clinicians, legal expert or retired judge, social activist, philosopher, head of the institution and a lay person. The levels of review conducted by the IRB consists of

- Exempt from interview – is for those studies that pose minimal risk
- Expedited interview – is for that pose a little more than minimal risk
- Complete interview – for research that cannot be exempted or expedited. [12,13]

COMMON ETHICAL ISSUES

While conducting health or biomedical research, the most encountered ethical issues are; [14]

1. Risk-benefit assessment
   This is a means of safe guarding the study population. The appraisal is designed to weigh positive outcomes against risks involved. Whether the study is going to benefit human race is the pertinent fact that determines carrying out the study. Apart from this essential question the other positive outcomes that favour conducting the study are;
   - Access to better intervention that would be unavailable to the population if not for the study.
   - Increased awareness about the condition or disease that has affected the subjects.

- Monetary benefit to the participants.
- A general sense of accomplishment of being enrolled in a study that is for the benefit of human kind.
- A way of emotional venting regarding their disease condition and getting advice.

These above-mentioned advantageous outcomes have to be compared against the harms that are caused by the study such as;

- Side effects that could cause physical harm.
- Fatigue, discomfort or losing interest.
- Emotional stress caused by sharing personal information and experiences.
- Time taken out of employment hours.
- Compromise of privacy.
- Effect on personal life or social stigma
- Monetary loss for commuting and missing from work.

After the careful consideration of all factors, research is undertaken only if the benefit – risk ratio is favourable.

2. Informed consent process
   Obtaining informed consent is essential for every trial involving human subjects. Information regarding the trial should be explained in simple and understandable language that facilitates informed decision making. The informed consent form should comprise of the following to be comprehensive.
   - Purpose and nature of the research
   - Duration of the study with the expected number of subjects
   - Procedures that are going to be performed
   - Particulars of the investigations that might be performed
   - Expected discomfort or risks that might be experienced by participants
   - Positive outcomes of the intervention to the community
   - Terms and particulars of compensation
   - Information regarding medical treatments that are available for risk management
   - Alternative treatment options available
   - Steps that are taken for guaranteeing confidentiality
   - Assurance of benefit even after withdrawing from the study
   - Include contact details of primary investigator for further clarifications regarding the trial.
   - Include contact details of chairman of IEC for appeal regarding violations

   The consent form should bear the signature or thumbprint of the study subject procured in presence of a witness.
3. Privacy and confidentiality
   Researchers have to protect the confidentiality of the participant especially data that can disclose the identity of the individual. It can be disclosed only under special circumstances such as
   - Order by court of law
   - Threat to life of the person
   - To communicate regarding severe adverse reaction to the drug
   - Circumstance of public health emergency
4. Compensation of harm caused by research
   In case of any physical harm resulting in temporary or permanent disability, the participants are entitled to monetary compensation. The issue of compensation has to be decided a *priori* by the ICE. Arbitration of the same can be done by appellate committee set up by the concerned institution.
5. Ancillary care
   Medical coverage for providing treatment free of cost irrespective of the disease under study is the moral and social responsibility of the researchers.
6. Therapeutic misconception
   This occurs when a subject enrolls into the trial without understanding the real intent of the study. Hence researchers should provide a clear and detailed explanation regarding the trial in order to obtain an ethical informed consent.
7. Conflict of interest

Those conditions that interfere with the primary interest pertaining to well-being of the patient but rather is motivated by secondary interests like academic recognition or monetary gain are labelled as Conflict of Interest. Hence all research conducted through sponsorship or funding by commercial companies should be evaluated diligently by IEC to weigh scientific benefits versus commercial gains. Conflict of interest has to be declared by the researchers before the ethical review where, the IEC should take necessary SOP to ensure welfare of the study subjects. The participants also have to be informed regarding sponsors or funding of research and be made aware of conflict of interest.

8. Selection of participants from special or vulnerable groups
   Individuals with reduced capacity to consent, belonging low social class, children, uneducated, tribals, pregnant women who are unable to protect their interests and welfare are considered vulnerable population. All ethical bodies including Declaration of Helsinki stand against exploitation of these groups. Including these populations in research is warranted only after consultation with the representative of the group and if outcomes target to benefit these groups specifically. The IEC has to ensure that research on these groups is justifiable.
9. Benefit sharing and post research access
   Most of the developed countries collect data regarding new drugs from the developing and developed countries. Hence, it is mandatory that participating populations of these countries have access to post trial data regarding the best therapeutic measure. This has to be ascertained by the IEC through *a priori* arrangement. [15]

CONCLUSION

Ethics plays a significant role in modern research. Safe guarding the welfare of study participants should be the primary concern of every research undertaken. Importance of ethics in research can be summarised as

- Safeguard's well-being of vulnerable groups and in general all study participants.
- Establishes a risk-benefit ratio.
- Ensures complete respect of privacy and dignity of the subjects.
- Creates opportunity for participants to reject or accept enrolment in a study

If research is based on a safe and ethical manner and a vigorous design, it can be of benefit to all. Ultimate determinant rests with researcher's value system and moral code but professional codes, laws, regulations, and ethics committees can provide guidance. Law is not a source of dread or obstacle to professional services. The profession should correct malpractice from within. Dental and Medical councils should be more attentive and make sure that prestige of our profession is not lost.

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REFERENCES

1. Knottnerus JA, Tugwell P. (2018). Ethics of research methodology requires a methodology of research ethics. Journal of Clinical Epidemiology. 100: 5-6.
2. Shamy M, Fedyk M. (2018). Why the ethical justification of randomized clinical trials is a scientific question Journal of Clinical Epidemiology.97: 126-132
3. Resnik DB. (2021). What is ethics in research and why is it important? https://www.niehs.nih. gov/research/resources/bioethics/whatis/index.cfm?links=falselast accessed.
4. The Belmont Report: What is it and how does it relate to today's clinical trials? Available at https://www.cancer support community. org/blog/2019/10/belmont-report-what-it-and-how-does-it-relatelast.
5. The Belmont Report. Available at https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html last accessed at 10:25pm on 15.04.2021
6. Research Methods – Ethics in research; What is research ethics? Available at https://libguides.library. cityu.edu.hk/research methods/ethics - s-lg-box-8893255 last accessed at 08:28pm on 16.04.2021
7. Five principles of research ethics; Cover your bases with these ethical strategies. Available at https://www.apa.org/monitor/jan03/principles last accessed at 09:17pm on 15.04.2021
8. Sanmukhani J, Tripathi CB. (2011). Ethics in clinical research: The Indian perspective. Indian Journal Pharmaceutical Science. 73(2): 125-130
9. Mzayek F. Resnik D. (2010). International biomedical research and research ethics training in developing countries. Journal of Clinical Research and Bioethics. 1: 103. DOI:10.4172/2155-9627.1000103

10. Ethical guidelines for biomedical research on human participants. Available at https://nischennai.org /uploaded/pdf/ICMR%20ethical_guidelines.pdf last accessed at 07:17pm on 16.04.2021
11. Handbook on National Ethical guidelines for biomedical research on human participants. Available at https://ethics.ncdirindia.org//asset/pdf/Handbook_on_ICMR_Ethical_Guidelines.pdf last accessed at 07:22pm on 16.04.2021
12. Das NK, Sil A. (2017). Evolution of ethics in clinical research and ethics committee. Indian Journal of Dermatology ; 62(4): 373-379.
13. Thatte UM Marathe PA. (2017). Ethic committees in India: Past, present and future. Perspectives in Clinical Research; 8(1): 22-30.
14. National Ethical guidelines for biomedical research on human participants. Available at https://main.icmr.nic.in /sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf.
15. Usharani P, Naqvi SMH. (2013). Post-trial access. Perspectives in Clinical Research. 4(1): 58-60.