Content available at: https://www.ipinnovative.com/open-access-journals

IP International Journal of Medical Paediatrics and Oncology

Journal homepage: https://www.ijmpo.com/

Review Article

Research and publication ethics - Need for introspection

Vishnu Bhat Ballambattu[1]*, **Krishna Rao Gurugubelli**[2]

[1]*Dept. of Pediatrics & Neonatology, Aarupadaiveedu Medical College and Hospital, Vinayaka Mission's Research Foundation-DU, Kirumampakkam, Puducherry, India*
[2]*Dept. of Biochemistry, Andhra Medical College (AMC), Visakhapatnam, Andhra Pradesh, India*

ARTICLE INFO

Article history:
Received 27-10-2024
Accepted 02-12-2024
Available online 20-12-2024

Keywords:
Research ethics
Belmont report
Research misconduct
Publication ethics

ABSTRACT

Research ethics provides appropriate guidelines for conducting research. Additionally, it ensures that scientists doing research adhere to high ethical standards set by the institutional ethics committee by educating and monitoring them. It is crucial that all research initiatives strictly adhere to ethical principles. Ethics is the set of rules that determine how someone should behave while conducting an activity. Professional organizations set the standards to be followed during research to avoid any harm to the trial subjects. It is the responsibility of the ethics committee to closely monitor the progress of research until the study is completed. If the researcher does not follow the guidelines, he can be reprimanded by the ethics committee, and they can also recommend other suitable remedial measures including stopping of the study. While conducting research, all ethical principles should be taken into consideration. This review discusses the fundamental ethical principles mentioned in the Belmont report i.e., autonomy, beneficence, justice and equality. It briefly covers research misconducts like fabrication, falsification of data, plagiarism and publication ethics.

1. Introduction

Research ethics and its application in practice are essential for avoiding any possible misconduct with the scientific method or the way results are communicated to the public, which could affect patient outcomes and the researcher's position.[1] Research involving human subjects has a big historical shadow due to a number of unethical research experiments carried out worldwide. Studies at Willowbrook state school in the 1950s and 1960s, Nazi medical experimentation in the 1930s and 1940s, and the Tuskegee Syphilis Study from 1932 to 1972 and a recent declaration of Taipei are a few examples. The necessity of regulations controlling the planning and execution of research protocols involving human subjects should be transparent. The Nuremberg guideline was the first research ethics guideline, established in the wake of Nazi research activities exposed during the Nuremberg trials following World war II.[2,3] Legal guidelines are developed by the Government in order to provide balance in society and protection to its citizens. The law tries to create a basic, enforceable standard of behavior necessary for a community to succeed and people to live with equality. The law enforcement authority may prescribe punishment for not following the rules.

2. Discussion

2.1. Principles of universal ethics

The clinical trial conduct is influenced by three fundamental ethical principles that were specified in the Belmont Report.

* *Corresponding author*.
E-mail address: drvishnubhat@yahoo.com (V. B. Ballambattu).

https://doi.org/10.18231/j.ijmpo.2024.021

The first is respect for the individual, which includes recognizing people as free agents and defending those with less freedom. The idea is the basis for the necessity that informed consent be obtained before taking part in clinical research. The second principle, beneficence, states that, "first, do no harm," efforts should be made to ensure the welfare of study participants by optimizing potential benefits by avoiding potential hazards. Thirdly, justice relates to the impartial and unbiased selection of research participants, ensuring that all qualified individuals, irrespective of their financial status, disability, race, or ethnicity, gender have an equal chance to take part in clinical trials and receive research findings that are useful to them.[3,4]

The Belmont Report also describes research-based protective applications for participant selection, risk/benefit analysis, and informed consent.[5]

2.1.1. Autonomy

The Respect for individual principle, also referred to as human dignity, is the first protective principle that emerged from the Belmont Report. This means that researchers must endeavour to safeguard the autonomy of research participants and guaranteeing complete disclosure of all study-related information like possible risks and advantages. In accordance to Belmont report, every individual has a right to autonomy. The researcher has an obligation to disclose all information to the participant so that the research subjects can take the decision to participate or not in the study.[2,6] There are variety of ethical principles that ought to be taken under consideration when performing research. In practice, these ethical principles mean that as a researcher, one would like to get consent from potential research participants, minimize the danger of harm to participants, protect their anonymity and confidentiality, avoid using deceptive practices, and give participants the right to withdraw from your research at any time without fear of penalty.[7] Not everyone is able to independent decision to participate in research. Some people need special research protections, which may include excluding them from potentially harmful research activities or designating a legal guardian to supervise their participation, depending on their developmental stage, various illnesses, or disabilities.[8] Additionally, researchers must make sure they don't force possible subjects to consent to study participation. Threats of punishment, whether explicit or implied, for refusing to participate in or opt out of a study are referred to as coercion. In few occasions there is a possibility to provide incentives to the study participants. The incentives could be so attractive that makes the individual to participate in the study. On the other hand, if no such reward has been provided, they would have refused to take part in the study. This possibility of coercion needs to be examined. The eligible volunteers may be coerced into participating in a study by certain incentives, depriving them of their autonomy.[9] In order to respect the autonomy of potential participants, researchers must make sure that all relevant information like voluntary nature of participation (Right to decline without consequence) and the potential risks and benefits of taking part in the study has been provided. In the absence of comprehensive information, a prospective participant cannot make an informed decision. Depending on their research topics and study designs, some researchers may find the Belmont report problematic. It has been observed that biases may arise when study participants are aware of the precise research questions and objectives. By adopting confidential methods for data collection or hiding important study information, some researchers can prevent biases. Because awareness of receiving a placebo can impact research results, masking is common in pharmacological trials that use placebos. In such situations, participant autonomy and the related informed consent procedure may not be fully respected by masking and hidden data collection techniques. An Institutional review board must be consulted before any researcher planning concealed data collection or masking of study information from participants.[10]

2.1.2. Beneficence

The concept of beneficence is the second principle. For a study to be considered beneficial, researchers must minimize risks within the study procedure, protect study participants, and provide scientifically sound findings with practical applicability. Although a number of guidelines advise that research in low middle income countries (LMICs) concentrate on illnesses that significantly increase the local burden of disease, funders often define the goals of studies, which means that these rules are not always followed. In LMICs, where there is a high prevalence of cervical, liver, and gastric cancers, research on cancer treatments focuses on lung and breast cancer. Although there will always be some risk involved in trying new medications, research participants should anticipate that their group would benefit.[11,12]

Ethical research requires the use of a strict methodology with sufficient power and suitable control groups. Falsified data, poorly designed studies, and underpowered research are all unethical and will not produce reliable results. The earliest investigations of HIV transmission from mother to fetus and the use of placebo controls has been controversial. Patients should receive their usual local regimen if there is an effective treatment available, even though placebo-controlled trials are the best approach from a methodological perspective.[11,13] In their malaria trial, Cheah et al. present an excellent rationale for a placebo group because it is equal to current clinical practice and does not expose the individuals to greater risk.[14] In their study population, researchers should make sure that beneficial interventions will be sustained.[15]

Emergency and disaster scenarios may include the use of unproven interventions. A panel was created by the World Health Organization to coordinate the use of newer treatment modalities during epidemics.[16] They emphasize the significance of transparent and equitable decision-making processes for access to experimental therapies, as well as the necessity of thorough data collection to evaluate the efficacy and safety of such interventions. Reducing risk requires incorporating safety into the procedure and monitor the unfavourable outcomes during the trial. If there are adverse incidents, the trial may need to be stopped, unblinded, or reported to the human research ethics committee. Regardless of the trial's outcome, it is essential that all information be shared in order to protect future research participants from the risks of ineffective interventions and to allocate funds to initiatives that have a higher chance of improving health.[17]

Privacy protection is another important aspect under beneficence. Only members of the study team should have access to data. Paper records such as surveys must be stored in a lockable drawer and is kept secure. Passwords should be used to secure files. Personal identification numbers to be replaced with study ID numbers. Data cleaning should be followed by the destruction of master lists that might be used to trace data back to participants. Prior to sharing data with anyone outside the original study team, the individual identifiable details must be concealed. Verifying results and avoiding duplication of effort require data sharing, but laws and policies have not kept up with new developments in technology.[18,19]

2.1.3. Justice

The principle of justice, which deals with participants rights to privacy and equitable treatment, is the ultimate one in the Belmont report. Fair distribution of the expenses and rewards of research throughout to all people is necessary for justice. Since there are no universal standards for justice, even this statement is subject to interpretation.[20] A research study's targeted participant categories should be chosen based on its research objectives, which should be representative of the target population and avoid excluding any particular group. Institute review boards and researchers must carefully examine the selection of research participants and determine whether certain groups like those receiving public funding, members of particular racial and ethnic minorities, or institutionalized individuals are being deliberately chosen due to their vulnerability or accessibility.[9] In the context of clinical trials, the global distribution of research benefits and risks is problematic. Every year, millions of people take part in clinical research, but it is difficult to estimate the number of adverse events and they are probably underreported.[21,22] Clinical trial deaths are not fairly distributed throughout countries; LMICs have greater rates of morbidity and mortality. India recorded 2644 deaths during clinical trials between 2005 and 2012, but deaths in the global north are often uncommon and widely reported.[23]

Another possible hazard is compensation for research involvement. Western research ethics examine whether payment for involvement is sufficient to impose undue pressure or influence. Ironically, applying this norm to LMICs research would reduce the value of compensation because smaller sums would probably account for a higher share of participants income.[24] In the local context, participation gifts of nominal value, like soap or sugar, may have hidden implications and should be dealt with local authorities.[25] Considering participation as work and paying for it in accordance with local customs is one suggested remedy.[26] Inadequate transnational research disregards the sociocultural values of "researched" cultures, leaving participants and communities vulnerable to abuse and exploitation. This is true of participant and community remuneration as well as wider aspects of study procedure.[27]

The authorship of manuscripts is the last domain of justice. When outsiders approach a community to conduct study, there is an inherent power imbalance. In addition to making sure that each member of the study team is given the credit they deserve, researchers should work to strengthen local communities. A standardized set of authorship requirements was developed by the International committee of medical journal editors (ICMJE). The fundamental idea behind these criteria is that authorship is an intellectual activity that involves writing (editing the manuscript), contributing to ideas (study conceptualizing and research question framing), conducting analyses (developing the analysis approach/framework/conducting the actual analysis), and taking ownership (study or research project). Global health research journals are among the many biomedical and health publications that have embraced the ICMJE standards. Additionally, they have been updated regularly to address new issues and concerns.[28] According to the ICMJE, authorship should be determined by fulfilling each of the following four requirements: -[28,29]

1. Significant contributions to the work's idea or design; or the acquisition, processing, or interpretation of data for the project.
2. Critically rewriting or drafting the work to ensure it contains significant intellectual content.
3. Final acceptance of the published version.
4. Commitment to take responsibility for every aspect of the work, including the concerns about the integrity or accuracy of any part of it are thoroughly observed and addressed.

3. Research Misconduct

According to US government regulation, research misconduct is defined as plagiarism, data fabrication, or data falsification.[30]

3.1. Fabrication

Making up data or results and reporting them is known as data fabrication. Patient diaries and informed consent forms are the most frequently fabricated documents.[31]

3.2. Falsification

Manipulating research materials, or changing or omitting data or results such that the research is not accurately represented in the research record. Examples include studies that are published but not actually conducted, or studies that purposefully inflate the sample size to increase the study's credibility. It might be quite challenging to identify falsification. The researchers themselves can do this at the greatest level, while statisticians, lab assistants, and technicians can do it at the lowest level.[31]

3.3. Plagiarism

The appropriation of another person's ideas, processes, results, or words without giving appropriate credit amounts to plagiarism. The World association of medical editors defines plagiarism as the copying of six consecutive words or the overlapping of seven to eleven words in a group of thirty letters.[31,32] Plagiarism among students, researchers, and faculty members of all professions nowadays is mostly caused by the availability of internet resources and free online publications.[32] Plagiarism can be classified as:

Direct form: Completely or partially copying of text, computer files, audio or video recordings without acknowledging primary source.[31,32]

Mosaic form: Uutilizing concepts and viewpoints from the original source, as well as a few words and phrases without giving credit to the source.[31,32]

Self-plagiarism: When someone copies a part of their own writing for another piece of work.[31,32] Some have claimed that other forms of misbehaviour like sexual harassment, sabotage, deceptive use of statistics, failure to disclose conflict of interest should be included in the definition of research misconduct.[30]

4. Clinical Importance

The clinical knowledge of the reviewer is crucial for assessing how the data is presented ethically. One of the most important aspects of ethical and responsible research is the public's confidence in published studies. The fundamental assumption of all reviewers and editors who assess research is that the work was done honestly, that the reporting is open and honest, and that the researcher's integrity is unquestionable.[33]

An Institutional review board (IRB) or other external reviewers are among the most widely used protections for the ethical conduct of research. The IRB requires a complete research proposal from researchers who wish to start a study. This proposal must include precise data collection tools, research advertisements, and informed consent forms. The IRB may perform a complete or expedited review depending on the nature of the study and the risks involved. Until they receive complete IRB approval, researchers are not allowed to get in touch with possible volunteers or begin data collection. Occasionally, several IRB permissions are needed for multi-site research, and these approvals may have various forms and review procedures.[9]

IRB members are particularly interested in the study's use of individuals from vulnerable populations. People who are unable to provide fully informed consent or who may be more susceptible to unanticipated negative effects are examples of vulnerable groups. Individuals with mental or emotional problems, terminally sick patients, pregnant women, children under the age of consent, and institutionalized people are examples of vulnerable participants.[34] According to Subpart D of the Code of federal regulations, assent is another factor that needs to be considered when dealing with children. Although the study indicates that a minor could assent after the age of 7, there is an absence of information on when minors are capable of understanding research.[35] Researchers must take additional precautions whenever they include vulnerable groups in their studies in order to adhere to the ethical principles of the Belmont report, particularly beneficence.[9]

5. Conclusion

Research ethics provide responsible guidelines to conduct of research. In addition, it educates and monitors scientists conducting research to make sure of high ethical standard. It is important that all research activities are ethically sound. Ethics is the principle that govern a person's behavior in conducting an activity. It is governed by professional interactions and the standard is decided by professional bodies.

6. Conflict of Interest

None.

7. Source of Funding

None.

References

1. Correia MI. Ethics in research. *Clin Nutr Open Sci*. 2023;47:121–30.
2. Sims JM. A brief review of the Belmont report. *Dimens Crit Care Nurs*. 2010;29(4):173–4.

3. Vitti JN, Vitti R, Chu K, Mellis S. The ethics of clinical research in the era of COVID-19. *Front Public Health*. 2024;12:1359654. doi:10.3389/fpubh.2024.1359654.
4. 4.Department of Health, Education, and Welfare; National commission for the protection of human subjects of biomedical and behavioural research. The Belmont report. Ethical principles and guidelines for the protection of human subjects of research. *J Am Coll Dent*. 2014;81(3):4–13.
5. Cassell EJ. The principles of the Belmont report revisited. How have respect for persons, beneficence, and justice been applied to clinical medicine? *Hastings Cent Rep*. 2000;30(4):12–21.
6. Miracle VA. The Belmont Report: The Triple Crown of Research Ethics. *Dimens Crit Care Nurs*. 2016;35(4):223–8.
7. Franklin P, Rowland E, Fox R, Nicolson P. Research ethics in accessing hospital staff and securing informed consent. *Qual Health Res*. 2012;22(12):1727–38.
8. Chiong W, Leonard MK, Chang EF. Neurosurgical Patients as Human Research Subjects: Ethical Considerations in Intracranial Electrophysiology Research. *Neurosurgery*. 2018;83(1):29–37.
9. Cassell EJ. The principles of the Belmont report revisited. How have respect for persons, beneficence, and justice been applied to clinical medicine? *Hastings Cent Rep*. 2000;30(4):12–21.
10. Ghandour L, Yasmine R, El-Kak F. Giving consent without getting informed: a cross-cultural issue in research ethics. *J Empir Res Hum Res Ethics*. 2013;8(3):12–21.
11. Bitter CC, Ngabirano AA, Simon EL, Taylor DM. Principles of research ethics: A research primer for low- and middle-income countries. *Afr J Emerg Med*. 2020;10(2):125–9.
12. Silva RE, Amato AA, Andrade DD, Silva ALE, Carvalho MR, Novaes MR, et al. Research priorities and resource allocation in the investigation of new drugs for cancer in least developed countries. *J Oncol*. 2018;p. 8092702. doi:10.1155/2018/8092702.
13. Lurie P, Wolfe SM. Unethical trials of interventions to reduce perinatal transmission of the human immunodeficiency virus in developing countries. *N Engl J Med*. 1997;337(12):853–6.
14. Cheah PY, Steinkamp N, Seidlein L, Price RN. The ethics of using placebo in randomised controlled trials: a case study of a Plasmodium vivax antirelapse trial. *BMC Med Ethics*. 2018;19(1):19. doi:10.1186/s12910-018-0259-4.
15. Andanda P, Wathuta J. Human dignity as a basis for providing post-trial access to healthcare for research participants: a South African perspective. *Med Health Care Philos*. 2018;21(1):139–55.
16. World Health Organization. Ethical considerations for use of unregistered interventions for Ebola virus disease (EVD); 2014. Available from: https://www.who.int/news/item/12-08-2014-ethical-considerations-for-use-of-unregistered-interventions-for-ebola-virus-disease-(evd).
17. Mlinarić A, Horvat M, Smolčić V. Dealing with the positive publication bias: Why you should really publish your negative results. *Biochem Med (Zagreb*. 2017;27(3):03020. doi:10.11613/BM.2017.030201.
18. Bull S, Cheah PY, Denny S, Jao I, Marsh V, Merson L, et al. Best Practices for Ethical Sharing of Individual-Level Health Research Data From Low- and Middle-Income Settings. *J Empir Res Hum Res Ethics*. 2015;10(3):302–13.
19. Georgiou A, Magrabi F, Hyppönen H, Wong ZS, Nykänen P, Scott PJ, et al. The Safe and Effective Use of Shared Data Underpinned by Stakeholder Engagement and Evaluation Practice. *Yearb Med Inform*. 2018;27(1):25–8.
20. Schäfer M, Haun DB, Tomasello M. Fair Is Not Fair Everywhere. *Psychol Sci*. 2015;26(8):1252–60.
21. Shamoo AE. Adverse events reporting–the tip of an iceberg. *Account Res*. 2001;8(3):197–218.
22. Earley A, Lau J, Uhlig K. Haphazard reporting of deaths in clinical trials: a review of cases of clinicaltrials.gov records and matched publications - a cross sectional study. *BMJ Open*. 2013;3(1):1963. doi:10.1136/bmjopen-2012-001963.
23. Biswas R. Over 2,500 Deaths During Indian Clinical Trials; 2019. (Retrieved on March 18, 2019). Available from: https://www.ipsnews.net/2013/11/over-2500-deaths-during-indian-clinical-trials/.
24. Gelinas L, Largent EA, Cohen G, Kornetsky S, Bierer B, Lynch HF, et al. A framework for ethical payment to research participants. *N Engl J Med*. 2018;378(8):766–71.
25. Biruk C. Ethical gifts? An analysis of soap-for-data transitions in Malawian survey research worlds. *Med Anthropol Q*. 2017;31(3):365–84.
26. Davidson P, Page K. Research participation as work: comparing the perspectives of researchers and economically marginalized populations. *Am J Public Health*. 2012;102(7):1254–9.
27. Saleh S, Sambakunsi H, Nyirenda D, Kumwenda M, Mortimer K, Chinouya M, et al. Participant compensation in global health research: a case study. *Int Health*. 2020;12(6):524–32.
28. Sam-Agudu NA, Abimbola S. Using scientific authorship criteria as a tool for equitable inclusion in global health research. *BMJ Glob Health*. 2021;6(10):7632. doi:10.1136/bmjgh-2021-007632.
29. Zhou Q. Recommendations for the conduct, reporting, editing and publication of scholarly work in medical journals. *Zhonghua Gan Zang Bing Za Zhi*. 2014;22(10):781–91.
30. Resnik DB. Is it time to revise the definition of research misconduct? *Account Res*. 2019;26(2):123–37.
31. Deshmukh MA, Dodamani AS, Khairnar MR, Naik RG. Research misconduct: A neglected plague. *Indian J Public Health*. 2017;61(1):33–6.
32. Masic I. Plagiarism in scientific publishing. *Acta Informatica Medica*. 2012;20(4):208–13.
33. Dehart WB, Griffin E, Sundaram S, Wood BE, Flynn MG. An Introduction to Reviewing Research Articles for Academic Journals. *HCA Healthc J Med*. 2022;3(6):355–62.
34. Weisleder P. Helping Them Decide: A Scoping Review of Interventions Used to Help Minors Understand the Concept and Process of Assent. *Front Pediatr*. 2020;8:25. doi:10.3389/fped.2020.00025.
35. Wendler DS. Assent in paediatric research: theoretical and practical considerations. *J Med Ethics*. 2006;32(4):229–34.

Author's biography

Vishnu Bhat Ballambattu, Professor https://orcid.org/0000-0002-8856-7348

Krishna Rao Gurugubelli, Assistant Professor https://orcid.org/0000-0002-3124-8629

Cite this article: Ballambattu VB, Gurugubelli KR. Research and publication ethics - Need for introspection. *IP Int J Med Paediatr Oncol* 2024;10(4):78-82.