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**REVIEW PAPER**

# Legal and ethical issues of research and publication

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**ABSTRACT**

***Introduction****: Legal and ethical issues of research and publication form an important component of scientific writings, mainly related to the research participant, researcher and publication.* ***Methods****: Collecting anecdotes published in different newspapers and journal, this article seeks to briefly review the various international and national guidelines and regulations that exist on issues related to biomedical research and publication.* ***Discussion****: The issues of dignity, bodily integrity, autonomy and privacy, providing incentives of research participants and various forms of research misconduct and unethical practice in part of research activities are the burring issues discussed in present day scenario. Relevant international and national declaration and treaties form the literature that are relevant to the ethical and legal aspects of conducting research and publication that researchers should abide by when conducting biomedical research. Researchers should note the major international guidelines as well as the national regulations and legislation.* ***Conclusion****: Hence all proposals on biomedical research involving human participants should be cleared by an appropriately constituted local Institutional Ethics Committee (IEC).*

***Keywords****: Biomedical research, ethics, informed consent, plagiarism, scientific misconduct*

## INTRODUCTION

The conduct of biomedical research involving human participants raises a host of ethical and legal and political issues that have concerned philosophers, lawyers, policy makers, scientists, and clinicians for many years.[1]

The Declaration of Helsinki established ethical principles applied to clinical research involving human participants. The purpose of a clinical research is to systematically collect and analyse data from which conclusions are drawn, that may be applied, so as to improve the clinical practice and benefit patients in future.[2] Mastery and proficiency on the subject will help a medical writer in dealing with issues of research misconduct which might be challenging both in legal as well as ethical aspects in their experiments, studies and publication.[3]

Here in this article, a brief review on the legal and ethical issues on biomedical research involving human as research participant, basic principles of informed consent and precautions to be taken during collection of data in the process of clinical research and its publications were discussed.

## ISSUES RELATED TO THE RESEARCH PARTICIPANTS

The main role of human participants in research is to serve as sources of data. Researchers have a duty to 'protect the life, health, dignity, integrity, right to self-determination, privacy and confidentiality of personal information of research participants'.[4]All the research involving HPsshould be conducted in accordance with the **four basic ethical principles**, namely:

- **Autonomy** (respect for person)- Acknowledge a person's right to make choices, to hold views, and to take actions based on personal values and beliefs.
- **Beneficence** (do well) - Provide benefits to persons and contribute to their welfare. Refers to an action done for the benefit of others.
- **Non-maleficence** (do no harm) - Obligation not to inflict harm intentionally; In medical ethics, the physician's guiding maxim is "First, do no harm."
- **Justice -** Treat others equitably, distribute benefits/burdens fairly.

Mistreatment of research participant is considered as research misconduct viz., no ethical review approval, failure to follow approved protocol, absent or inadequate informed consent, exposure of subjects to physical or psychological harm, exposure of subjects to harm due to unacceptable research practices or failure to maintain confidentiality, etc.[5] There is also scientific

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misconduct involving fraud and deception.

There is also scientific misconduct which involves fraud and deception.[3] **Scientific misconduct** means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research[6] are also increasing in modern day research and publications.

**Informed consent**

Informed consent should be looked on as a process rather than a signature on a form. This process includes a mutual sharing of information over a time between the clinician and the patient to facilitate the patient's autonomy in the process of making ongoing choices.[8] To be valid informed consent the **s**ubject must be competent, researcher must give a full disclosure, subjects must understand what the researcher tells them and subject's decision to participate must be voluntary. Consent taken from the patient for trial of drug or therapy which is not as per the guidelines of ICMR shall also be construed as misconduct.[12]

However, additional relevant information must be provided in clinical trials or research studies in informed consent form as shown in **Table 1** [Adapted from International Conference on Harmonisation (ICH) Harmonised Tripartite Guideline, Guideline for Good Clinical Practice E6 (R1)].[9]

**Table 1** Essential components of an informed consent[9]

| |
|---|
| A statement mentioning the study that involves research |
| Study information: Protocol title, name and contact details of principal investigator, funding resources of the study |
| The purpose of the research study and the duration of the participation |
| The study procedures and visit schedule |
| The participants' responsibilities in the study |
| What happens if the participant withdraws from the study |
| A clear statement what is experimental in the study |
| A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject |
| The possible risks, discomforts and inconveniences in the study |
| The potential benefits for the participants |
| The participants' rights |
| The extent of confidentiality of study and medical records |
| Any cost of participation |
| Possible researchrelated injury and compensation (including insurance coverage to provide treatment for injury arising from participation) |
| A statement that the subject or the subject's legally acceptable representative will be informed in a timely manner if additional information becomes available |
| The contact details if participants have questions regarding the study or regulatory policy |
| The approximate number of subjects involved in the trial |

All the relevant information should be given in the language and method that individual participant can understand[4] commonly in the form of a printed '**Participant Information Sheet**'. The research participants must be informed about the right to refuse to participate or withdraw consent to participate at any time without reprisal and without affecting the patient–physician relationship. There are also general principles regarding risk assessment, scientific requirements, research protocols and registration, function of ethics committees, use of placebo, post-trial provisions and research publication.[4]

**Special population**

There is nothing wrong in obtaining informed consent from a subject if he or she is above 12 years of age, conscious and mentally sound and which is given freely, voluntarily and directly without fear, force or fraud (Sec. 88IPC). However, informed consent should be sought from a legally authorised representative if a potential research subject is incapable of giving informed consent or is unconscious or is insane (Sec. 89IPC).[4] The 'legally authorised representative' may be a spouse, close relative, parent, power of attorney or legally appointed guardian. The hierarchy of priority of the representative may be different between different countries and different regions within the same country; hence, local guidelines or laws should be consulted.[2]

**Emergency medical condition and consent for research**

Emergency research studies occur where potential subjects are incapacitated and unable to give informed consent (acute head injury, cardiac arrest). The Council for International Organisations of Medical Sciences/World Health Organisation guidelines and Declaration of Helsinki make exceptions to the requirement for informed consent in these situations[4, 9] which has minor variations in laws governing the extent to which the exceptions apply in these situations.[10]

Every effort should have been made to find a legal authority for obtaining consent failure to which and if not enough time is available an 'exception to informed consent' may allowed the subject to be enrolled with prior approval of an ethical committee.[9] Researchers must obtain informed consent retrospectively as soon as possible from the subject on regaining his consciousness, or from their legal gradients when available, for continued participation of the research.[4, 9]

**Data collection and maintenance of confidentiality**

As per 'The Health Insurance Portability and Accountability Act' there are requirements for informed consent disclosure and standards for electronic exchange, privacy and information security. In the UK, generic legislation is found in the 'Data Protection Act'.[11]

The International Committee of Medical Journal Editors (ICMJE) recommendations suggest that authors must ensure that non-essential identifying information (names, initials, hospital record numbers) are omitted during data collection and storage wherever possible. Where identifying information is essential for scientific purposes viz., clinical photographs, written informed consent must be obtained and the patient must be shown the manuscript before publication. Subjects should also be informed if any potential identifiable material might be available through media access.However, if his or her identity is distorted then no need to have consent.

**Providing incentives**: Cash or other benefits 'in-kind' (financial, medical, educational, community benefits) should be made known to subjects when obtaining informed consent without emphasising too much on it.[9] Benefits may serve as appreciation or compensation for time and effort, but should not result in the inducement to participation.[13] The amount and nature of remuneration should be compared to norms, cultural traditions and are subjected to the Ethical Committee Review.[9]

A medical practitioner (MP) may carry out, participate in, work in research projects funded by pharmaceutical and allied healthcare industries.The MP is obliged to know the fulfillment of certain criteria's mentioned in **Table 2** which will be a necessity for undertaking any research assignment/project funded by industry– for being proper andethical.[12]

**Table 2** Criteria as per Chapter 8:8(e) medical research[12]

| | |
|---|---|
| i. | Ensure that the particular research proposal(s) has due permission from the competent concerned authorities. |
| ii. | Ensure that such a research project(s) has the clearance of national/state/institutional ethics committees/bodies. |
| iii. | Ensure that it fulfills all the legal requirements prescribed for medical research. |
| iv. | Ensure that the source and amount of funding is publicly disclosed at the beginning itself. |
| v. | Ensure that proper care and facilities are provided to human volunteers, if they are necessary for the research project(s). |
| vi. | Ensure that undue animal experimentations are not done and when these are necessary they are done in a scientific and a humane way. |
| vii. | Ensure that while accepting such an assignment a medical practitioner shall have the freedom to publish the results of the research in the greater interest of the society by inserting such a clause in the MOU or any other document/agreement for any such assignment. |

## ISSUES RELATED TO THE RESEARCHERS

### Ethical guidelines for biomedical research

All institutions in the India, which carry out any form of biomedical research (BMR) involving human as research participant (HP), should follow the ICMR guidelines in letter and spirit to protect the safety and well-being of all individuals.It is mandatory that all proposals on BMR involving HP should be cleared by an appropriately constituted **Institutional Ethics Committee** (IEC).[14]

### Avoiding bias, inappropriate research methodology, incorrect reporting and inappropriate use of information

Good, well-designed studies advance medical science development. Poorly conducted studies violate the principle of justice, as there are time and resources wastage for research sponsors, researchers and subjects, and undermine the societal trust on scientific enquiry.[15] The Guidelines for Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials.[16]

### Scientific misconduct

*De novo* data invention (fabrication) and manipulation of data (falsification)[7] constitute serious scientific misconduct. The true prevalence of scientific fraud is difficult to measure;however, it is about 2%–14%.[17]

### Plagiarism

Plagiarism is the use of others' published and unpublished ideas or intellectual property without attribution or permission and presenting them as new and original rather than derived from an existing source.[18] Tools such as similarity check[19] are available to aid researchers detect similarities between manuscripts, and such checks should be done before submission.[20] Self-Plagiarism is the verbatim copying or reuse of one's own research (IEEE Policy statement). Both types of plagiarism are considered to be unacceptable practice by most scientific publications. Plagiarism is a growing burning problem in **scientific research** and probably the commonest ethical issue **corrupting** medical writing. It threatens the **integrity** of **academic research and publication**. There are evidences that it handicaps the true findings. It also violates the code of Medical Ethics Regulations, 2002.

### Overlapping publications

Duplicate publications violate international copyright laws and waste valuable resources.[21, 22] Such publications can distort evidence-based medicine by double-counting of data when inadvertently included in meta-analyses.[21] This practice could artificially enlarge one's scientific work, distorting apparent productivity and may give an undue advantage when competing for research funding or career advancement.[22]

### Duplicate publication, redundant publication

Publication of a paper that overlaps substantially with one already published, without reference to the previous publication.[15]

### Salami publication

Slicing of data from a single research process into different pieces creating individual manuscripts from each piece to artificially increase the publication volume.[21] Such misconduct may lead to retraction of articles.

### Research Misconduct

Clinical drug trials or other research involving patients or

volunteers as per the guidelines of ICMR can be undertaken, provided ethical considerations are borne in mind. Violation of existing ICMR guidelines in this regard shall constitute misconduct in India.[12]

**Copyright**

Usually, sponsors and authors are required to sign over certain publication rights to the journal through copyright transfer or a licensing agreement; thereafter, authors should obtain written permission from the journal/publisher if they wish to reuse the published material elsewhere.[7]

**Issues related to authorship**

The ICMJE recommendation lists four criteria of authorship:

1. Author must substantially contribute to the conception, designing of the work, acquisition, analysis, or interpretation of data related to the study
2. Not only drafting of the work, but also revising it judgmentally for drawing scholarly content;
3. Have to approve the final version of the paper for publication and
4. Agreement to the accountability of all related aspects of the study in regards to integrity and accuracy of the topic investigated there of and resolved.

The researchers and authors have an ethical as well as legal obligation to ensure the accuracy of data, publication and dissemination of the result of research.[4] The author should disclose the relevant corrections, retractions and errata, to protect scientific integrity of published evidence to the journal, etc. Sponsors of clinical trials must allow all study data set for publication.[23]

**Contributors other than author**

The contributors of the manuscript who does not qualify any criteria as mentioned by ICMJE for authorship should not be mentioned as co-author, etc. All those should be acknowledged duly in the acknowledgement section after the conclusion. For example: Acquisition of funding, writing assistance, technical editing, language editing, proof reading, general supervision of a research group and general administrative support. Their contribution must specify in the declaration, i.e., served as scientific advisors,critically reviewed the research proposal,collected and complied data,participated in writing or technical editing of the manuscript, etc.[24] The author should also declare the potential conflicts of interest. The Council of Scientific Editors has identified several inappropriate types of authorship, such as guest authorship, honorary or gift authorship and ghost authorship.[7]

## CONCLUSION

Concerns regarding ethical and legal issues in relation to research and publication has increased day by day with due increase of research activities. The guidelines laid down by different organizations and authorities both at international and national level serve as a guide to promote integrity, fulfilment of ethical and legal standards in the conduct of research as well as in publication.

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