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ETHICAL ISSUES IN ACADEMIC RESEARCH IN INDIA

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Abstract

Ethics are broadly the set of rules, written and unwritten, that govern our expectations of our own and others' behaviour. Effectively, they set out how we expect others to behave, and why. While there is broad agreement on some ethical values (for example, that murder is bad), there is also wide variation on how exactly these values should be interpreted in Practice. An attempt is made in this paper to explain the Ethical Issues in Academic Research in India.

Keywords: Ethics, Academic, Research and confidentiality.

Introduction

Legal and ethical issues form an important component of modern research, related to the subject and researcher. This article seeks to briefly review the various international guidelines and regulations that exist on issues related to informed consent, confidentiality, providing incentives and various forms of research misconduct. Relevant original publications (The Declaration of Helsinki, Belmont Report, Council for International Organisations of Medical Sciences/World Health Organisation International Guidelines for Biomedical Research Involving Human Subjects, World Association of Medical Editors Recommendations on Publication Ethics Policies, International Committee of Medical Journal Editors, CoSE White Paper, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use-Good Clinical Practice) form the literature that are relevant to the ethical and legal aspects of conducting research that researchers should abide by when conducting translational and clinical research. Researchers should note the major international guidelines and regional differences in legislation. Hence, specific ethical advice should be sought at local Ethics Review Committees.

The word 'ethics' is derived from the Greek word, ethos, which means custom or character. Ethics is the systematic study of values, so as to decide what is right and what is wrong. In clinical research human beings are involved, as opposed to animals, atoms or asteroids, as the object of study. It focuses on improving human health and well-being, typically by identifying better methods to treat, cure or prevent illnesses. Ethics in clinical research focuses largely on identifying and implementing the acceptable conditions for exposure of some individuals to risks and burdens for the benefit of the society at large.

Development of Various Ethical Guidelines - Changing Scenario

The Nuremberg code was not honored by some researchers and there continued to be abuses and exploitations of humans in research. The Willowbrook State Study to know natural course of infective hepatitis in children and the Jewish Chronic Disease Hospital study to understand body's ability to reject cancer cells in debilitated subjects were

examples of unethical research. This led the World Medical Association (WMA) to develop a set of guidelines to safeguard the rights and well being of participants in clinical research. The set of guidelines was adopted by the 18th WMA General Assembly and was called the Declaration of Helsinki. It was revised five times and the latest version was published in 2000 at the 52nd WMA, Edinburgh, Scotland. It contains 32 principles, which stress on informed consent, confidentiality of data, vulnerable population and requirement of a protocol, including the scientific reasons of the study, to be reviewed by the ethics committee.

In the United States the ethical guidelines were setup after the discovery of the Tuskegee Syphilis Study. The study was started in 1932 with 399 syphilitic African American men to see the natural course of syphilis and was supposed to last for about six months but as the researchers were getting "good data" they decided to continue it. The participants were misled and deprived of treatment even after the introduction of penicillin in the 1940s. These ethical atrocities were exposed in 1972 resulting in discontinuation of the study, but till then it had already led to 28 deaths and permanent disability in 100 subjects; moreover 40 patients infected their wives resulting in 19 cases of congenital syphilis. To probe into the study the 'National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research' was formed which wrote the Belmont Report in 1979 and laid the foundation for regulations regarding ethics and human subjects' research in the US. The Belmont report stressed upon three basic ethical principles: respect for person, beneficence and justice. These were applied in the form of informed consent, assessment of risks and benefits by ethics committees and selection of subjects. With the increasing interest of pharmaceutical industries in carrying out research experiments in the developing and the under developed countries, in 1982, the Council for International Organizations of Medical Sciences (CIOMS) in association with World Health Organization (WHO) developed 'International Ethical Guidelines for Biomedical Research Involving Human Subjects'. They especially stressed upon ethical issues in less developed countries like investigator's duties regarding consent, appropriate inducements, special/ vulnerable populations, therapeutic misconceptions and post trial access.

The Indian Perspective

The Indian Council of Medical Research (ICMR), in February 1980, released a 'Policy Statement on Ethical Considerations involved in Research on Human Subjects'. This was the first policy statement giving official guidelines for establishment of ethics committees (ECs) in all medical colleges and research centres. But as with other nations of the world, these guidelines were not respected by many researchers and India was not free of controversial research works. In 1970s and 1980s researchers at the Institute for Cytology and Preventive Oncology in New Delhi, carried out a study on 1158 women patients of different stages of cervical dysplasia or precancerous lesions of the cervix. These patients were left untreated to see how many lesions progressed to cancer and how many regressed. By the end of the study seventy one women had developed malignancies and lesions in nine of them had progressed to invasive cancer. Sixty-two women were treated only after they developed localised cancer. After the controversy about the study became public in 1997, the ICMR started developing 'Ethical Guidelines for Biomedical Research on Human Subjects' and finalised them in the year 2000. These are a set of guidelines which every researcher in India should follow while conducting research on human subjects. Although not a law, these guidelines have been put into force through Schedule Y.

Issues Related to the Researcher

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 subjects'.The Belmont Report also provides an analytical framework for evaluating research using three ethical principles:

1. Respect for persons – the requirement to acknowledge autonomy and protect those with diminished autonomy
2. Beneficence – first do no harm, maximise possible benefits and minimise possible harms
3. Justice – on individual and societal level. Mistreatment of research subjects is

considered research misconduct (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). There is also scientific misconduct involving fraud and deception.

- **Consent, possibility of causing harm**

Based on ICH definition, 'informed consent is a process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate'. As for a standard (therapeutic) intervention that carries certain risks, informed consent – that is voluntary, given freely and adequately informed – must be sought from participants. However, due to the research-centred, rather than patient-centred primary purpose, additional relevant information must be provided in clinical trials or research studies in informed consent form.

- **Special populations**

Informed consent may be sought from a legally authorised representative if a potential research subject is incapable of giving informed consent (children, intellectual impairment). The involvement of such populations must fulfil the requirement that they stand to benefit from the research outcome. 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 should be consulted.

- **Special case: Emergency research**

Emergency research studies occur where potential subjects are incapacitated and unable to give informed consent (acute head trauma, 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. There are minor variations in laws governing the extent to which the exceptions apply. Reasonable efforts should have been made to find a legal authority to consent. If there is not enough time, an 'exception to informed consent' may allow the subject to be enrolled with prior approval of an ethical committee. Researchers must obtain deferred informed consent as soon as possible from the subject (when regains capacity), or their legally authorised representative, for continued participation.

- **Collecting patient information and sensitive personal information, confidentiality maintenance**

The Health Insurance Portability and Accountability Act has 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.

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 (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.

- **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. Benefits may serve as appreciation or compensation for time and effort but should not result in the inducement to participation. The amount and nature of remuneration should be compared to norms, cultural traditions and are subjected to the Ethical Committee Review.

- **Legal issues pertaining to regulatory bodies**

Various regulatory bodies have been constituted to uphold the safety of subjects involved in research. It is imperative to obtain approval from the appropriate regulatory authorities before proceeding to any research. The constitution and the types of these bodies vary nation-wise. The researchers are expected to be aware of these authorities and the list of various bodies pertinent to India are listed in the article "Research methodology II" of this issue.

- **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.The Guidelines for GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials.

- **Fraud in research and publication**

De novo data invention (fabrication) and manipulation of data (falsification) constitute serious scientific misconduct. The true prevalence of scientific fraud is difficult to measure (2%–14%).

- **Plagiarism and its checking**

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. Tools such as similarity check are available to aid researchers detect similarities between manuscripts, and such checks should be done before submission.

- **Overlapping publications**

Duplicate publications violate international copyright laws and waste valuable resources. Such publications can distort evidence-based medicine by double-counting of data when inadvertently included in meta-analyses. 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. Examples of these practices include:

- **Duplicate publication, redundant publication**

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

- **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. Such misconduct may lead to retraction of articles. Transparent disclosure is important when submitting papers to journals to declare if the manuscript or related material has been published or submitted elsewhere, so that the editor can decide how to handle the submission or to seek further clarification. Further information on acceptable secondary publication can be found in the ICMJE 'Recommendations for the Conduct, Reporting, Editing, and Publishing of Scholarly Work in Medical Journals'.

- **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.

The Ethics Of Excellence:

Improving Academic Research

Improving academic research needs to be a wide-ranging project company will agree that academic research in India needs to be internationally competitive and our institutions feature in rankings lists. Global research and competition are now increasingly diverse and in this scenario, India rightfully wants to be an important player. In pedagogy too, we face a situation of enhanced expectations. There has been a rapid expansion with the setting up of more Central and State universities which includes more focussed institutions such as the Indian Institutes of Technology, Indian Institute of Science Education and Research, Indian Institutes of Management and National Institutes of Technology, enhancing the opportunities for high-quality teaching. Despite the impressive job being done, there is considerable room for improvement.

Excellence As Ethics

But what is still holding our nation back from achieving large-scale global academic excellence which is commensurate with our intellectual heritage and calibre? Beyond blaming the government and the bureaucracy, the usual suspects, it is important to look inward and ask whether our academics display an adequate ethical commitment to excellence. It is rarely appreciated that excellence is an ethical issue. We think of it as something arising from people of calibre coupled with sufficient resources. Consider this advertisement put out by Stanford University recently: "We seek exceptional individuals who can develop a world-class program of research, and have a strong commitment to teaching at both the graduate

and undergraduate levels." In such institutions, once an excellent candidate is identified, the institution does everything to convince her/him to accept the offer. Loss of the candidate to a rival institution is considered a serious failure, as excellence is seen to be a precious commodity, with the heads of such institutions held accountable.

In India, in contrast, excellence is at best one of multiple criteria in faculty hiring. Though never openly stated, extraneous considerations abound. It is an open secret that these considerations define a large fraction of hiring across India, and often precede considerations of merit. In some places, excellence can actually go against the candidate.

The Faults Within

One might be tempted to solely blame failed institutions/departments on the calibre of leadership, and, ultimately, the government that appoints such leaders. But the problem persists even in those institutions led by respected academics. The reasons need to be examined. While academics freely criticise personality cults in the political sphere, they are happy to cultivate those of their own. A few individuals, possibly achievers in their younger days, grow into collectors of awards and fellowships and dominate organisations and committees. Factions grow around them. These people, administratively overburdened out of their own choice, make serious judgments without adequate information. Conflict of interest is another, rarely highlighted, problem. For example, within an institution, the leader may provide partisan support for their own subject of expertise and restrain the progress of rivals.

The problem is not just confined to leaders. In many Indian institutions, there is increasing democratic participation of junior academics in hiring and promotions. One hopes that this would propel excellence to the top of the desirable attributes. Unfortunately even in this set-up, research areas that are of global importance are often, out of sheer ignorance, treated with disdain. This is a key point. In the ethics of excellence, ignorance cannot be an excuse. When making decisions affecting the future of one's institution, it is an ethical imperative to educate oneself on all the relevant facts. The atmosphere in which academics work has a profound impact on their achievements. Academic leaders need to offer support and mentorship but also impose a standard of excellence.

Many Most Ethical Codes Cover The Following Areas

- **Honesty and Integrity**

This means that you need to report your research honestly, and that this applies to your methods (what you did), your data, your results, and whether you have previously published any of it. You should not make up any data, including extrapolating unreasonably from some of your results, or do anything which could be construed as trying to mislead anyone. It is better to undersell than over-exaggerate your findings.

- **Objectivity**

You should aim to avoid bias in any aspect of your research, including design, data analysis, interpretation, and peer review. For example, you should never recommend as a peer reviewer someone you know, or who you have worked with, and you should try to ensure that no groups are inadvertently excluded from your research. This also means that you need to disclose any personal or financial interests that may affect your research.

- **Carefulness**

Take care in carrying out your research to avoid careless mistakes. You should also review your work carefully and critically to ensure that your results are credible. It is also important to keep full records of your research. If you are asked to act as a peer reviewer, you should take the time to do the job effectively and fully.

- **Openness**

You should always be prepared to share your data and results, along with any new tools that you have developed, when you publish your findings, as this helps to further knowledge and advance science. You should also be open to criticism and new ideas.

- **Respect for Intellectual Property**

You should never plagiarise, or copy, other people's work and try to pass it off as your own. You should always ask for permission before using other people's tools or methods, unpublished data or results. Not doing so is plagiarism. Obviously, you need to respect copyrights and patents, together with other forms of intellectual property, and always acknowledge contributions to your research. If in doubt, acknowledge, to avoid any risk of plagiarism.

Things to Consider about Ethics in Academic Research

Many values inherent in research are congruent with general moral and social values. They include things like human and animal rights, health and safety, honesty, respect and responsibility-to name just a few. If a researcher breaches their institution's established code of ethics, the consequences are often not only personal, they can be dire as well. For example, if one fabricates research findings, this act can jeopardize lives. Things are not always black and white with research ethics, if a few cases there are grey areas. Ethical dilemmas are therefore a part of research and need to be openly discussed and properly addressed. Make sure you protect you and your participants by following the code of conduct of your profession and/or your academic institution. Your research should be important to you (and your colleagues or research group), however, it shouldn't be prioritized over the well-being of others and/or the environment. As a researcher you should do your best to remain compassionate, Professionals, and also, to follow standards.

Ethical Principles Addressed in Many Codes of Ethics

There are specific codes, policies and rules that apply to research ethics and that are covered by different legal documents and codes of conduct. In Responsible Conduct of Research, the authors Adil E. Shamoo and David B. Resnik write about some of the main ethical principles we should all follow when engaging in research work. These include:

1. Honesty (for instance, in reporting and communicating your findings)
2. Objectivity (this minimizes bias)
3. Carefulness (for case, avoiding negligence)
4. Openness (when sharing data and discussing ideas)
5. Respect for intellectual property (acknowledging other people's work and giving everybody who participated credit),
6. Confidentiality (in connection with your participants and data)
7. Non-discrimination (against colleagues and students)
8. Competence (maintaining your continuous professional development standards)
9. Animal protection (unnecessary research or poorly designed research should not be performed on animals)
10. Legality (being familiar with institutional and federal guidelines and laws)

The research process becomes more complicated, and potentially contentious, when you involve animal or human subjects. Here is a brief overview of some of the important ethical considerations when working with human subjects.

Importance of Research Ethics

1. Research ethics are important for a number of reasons.
2. They promote the aims of research, such as expanding knowledge.
3. They support the values required for collaborative work, such as mutual respect and fairness. This is essential because scientific research depends on collaboration between researchers and groups.
4. They mean that researchers can be held accountable for their actions. Many researchers are supported by public money, and regulations on conflicts of interest, misconduct, and research involving humans or animals are necessary to ensure that money is spent appropriately.
5. They ensure that the public can trust research. For people to support and fund research, they have to be confident in it.
6. They support important social and moral values, such as the principle of doing no harm to others.