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Review Article

A CRITICAL INTERPRETATION OF ETHICS IN RESEARCH

Satender Khatri[1]*, Rajiv Bansal[2]
*[1]Assistant Professor, Department of Dravyaguna, Beehive Ayurvedic college, Dehradun, Uttarakhand.
[2]Assistant Professor, Department of Dravyaguna, Sanjeevani Ayurvedic medical College, Gajraula, Amroha, Uttar Pradesh, India.

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ABSTRACT

The moral standards that direct a person's behavior are known as ethics. Doing what is morally and legally correct in research is sometimes referred to as practicing research ethics. They are standards of behavior that set boundaries between what is morally correct and inappropriate. The article discusses the value of ethics in relation to organizing, carrying out, and disseminating research. Good Clinical Practice and several recommendations have been explored. The legal concerns that are pertinent to research procedures have been discussed in the essay. Researchers, ethics committees, and journal editors are just a few of the stakeholders who are very concerned about research misconduct and its consequences. The importance of research ethical awareness has been emphasized. **Methodology:** The material of research ethics has been collected from different, articles, authentic literatures, manuscripts, and authentic net sources, like NCBI, PubMed etc. **Conclusion:** For the researchers, a diligent mindset is crucial. To safeguard research participants from damage, it is crucial to uphold protocol compliance, informed consent processes, openness and integrity, confidentiality, and other standards.

INTRODUCTION

Researchers must follow ethical guidelines in order to conduct proper clinical research. These norms were created in great part as a reaction to flagrant transgressions of ethically acceptable conduct. There are egregious instances of unethical research practices, which have had detrimental effects on participants, researchers, and society at large. It is crucial to be aware of ethical concerns when organizing, carrying out, looking into the data, and employing research-related findings. Everyone participating in research, from individual researchers to funding agencies, central and institutional ethical committees, journal editors, participants, and the general public, has a duty for ethics.[1]

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Research is defined as "a process of discovery leading to new ideas, successfully disseminated," by The Research Excellence Framework, 2014. Research involves several stages. The research method revolves around ethics. At various stages of this process, researchers must address a variety of ethical considerations. The truth is that ethical issues might arise at any stage of the research process (Bickman & Rog, 2009).[2]

Moral principles largely dictate how research is conducted, even though only a few parts of research ethics have been spelled out in law. The relevance of ethical issues has grown significantly among the scientific community. The importance of ethical issues in social research has increased as a result of rising public concern about the scope of the investigation and changes to the law governing data privacy and human rights. The field of communication research has seen an increase in ethical concerns as a result of technology.[3]

Despite primarily involving human and animal participation, several social science disciplines include a range of methodologies and moral dilemmas. In addition to allowing the researcher's own ethical

judgements in addition to the professional ethics, ethical standards may also allow decisions to be guided by common values and experiences.[4]

Methodology

The material of ethics on research has been collected from different, articles, authentic literatures, Manuscripts, and authentic net sources, like NCBI, PubMed etc.

Historical Apprehension

Some of the most recent instances of unethical behavior might open your eyes. When his research team announced in 2004 that it had successfully cloned a human embryo and created stem cells from it, a method that one day could offer treatments for a variety of ailments, Hwang Woo-suk of South Korea was hailed as a national hero. Upon learning that a large portion of his stem cell research had been falsified, Hwang was charged with embezzlement and violating bioethics laws in 2006. He lost his position as a professor of theriogenology and biotechnology at Seoul National University, and the South Korean government stopped funding him and forbade him from doing stem cell research. In 2009, Hwang received a sentence of two years in jail with a suspension.[5]

Another prominent example that recently made headlines was that of Andrew Wakefield, a former British physician and medical researcher who was renowned for supporting the debunked theory that the measles, mumps, and rubella (MMR) vaccination causes autism and bowel illness. Wakefield was deemed to have "failed in his obligations as a responsible consultant," behaved against the interests of his patients, and conducted his published study "dishonestly and irresponsibly" by a General Medical Council (GMC) panel. His 1998 article was fully and promptly withdrawn by The Lancet. He was disqualified from practising medicine in the UK in May 2010 after an investigation found dishonest fabrication in the Lancet research.[6]

Concept of Ethics

Ethics may refer to the standards used to discriminate between right and wrong in a common-sense approach. Do unto others as you would have them do unto you, according to the Golden Rule. First and foremost, do no damage, the Hippocratic Oath states. According to the Ten Commandments, "Thou Shalt not murder" While all of these apply to research as well, there are more detailed rules for "ethics in research." The World Medical Association's Declaration of Helsinki is arguably the most significant of them. It was initially published in 1964 and most recently revised in 2008.[7]

There are several national and international organizations' that protect ethical standards in research. For instance, the World Medical Association, the National Research Ethics Service in the UK, the Office of Research Integrity in the US, the US Department of Health, and Human Services, etc. Journal editors who are having ethical issues can seek "self-assistance" from the Council on Publication Ethics (COPE). It was established in 1997 and now has more than 6000 members working across all disciplines. It listens to complaints from the public that a member has violated its code of conduct and offers editors and publishers guidance on publishing ethics. COPE reviews cases that have been anonymized, offers guidance, and keeps track of follow-up data in a database.[8]

The Food and Drug Administration (FDA), the National Institutes of Health, the General Medical Council, and other organizations also have direct or indirect responsibilities in the area of research ethics. But as was already mentioned, everyone is heavily involved in upholding the ethical standards of the research, including funding/sponsoring organizations, institutional ethics committees, and individual researchers like Chief Investigators, Principal Investigators, Research Associates, and Assistants.[9]

An Ethical Research

An excellent place to start when discussing research ethics is with the Nolan Committee's seven guiding principles for public life from 1995. These are leadership, openness, transparency, objectivity, selflessness, and integrity. Carefulness, respect for intellectual property, confidentiality, responsible publication, responsible mentoring, respect for colleagues, social responsibility, non-discrimination, competence, legality, animal care, and protection of human subjects are additional important principles that are pertinent to research.[10]

The Good Clinical Practice (GCP) guidelines are essential for upholding ethics throughout clinical studies. GCP is an international ethical and scientific quality standard for planning, carrying out, documenting, and reporting experiments in which human beings are involved. The Internal Conference on Harmonization (ICH) technical requirements for the licensing of medicines for human use is where it all began. The public is given assurance that the rights, safety, and well-being of trial participants are safeguarded when this standard is followed, in accordance with the values outlined in the Declaration of Helsinki, and that the clinical trial results are reliable. While creating clinical trial data that is meant to be submitted to regulatory bodies, this standard is followed. Other clinical research that can influence the

safety and welfare of human subjects may also use the ICH GCP's guiding principles.[11]

The ICH GCP has 13 guiding principles, which can be summed up as follows. 10 They emphasise conformity to the moral standards outlined in the Helsinki Declaration. Prior to starting a study, potential risks and drawbacks should be compared to the expected benefits for both the trial patient and society. The objectives of society and research should not take precedence over the rights, safety, and wellbeing of the trial participants. An experimental product's nonclinical and clinical data should be sufficient to justify the suggested clinical study. Scientifically sound clinical studies should be explained in a precise, comprehensive protocol.[12]

A study should be carried out in accordance with the protocol that has previously gained permission from the independent ethics commission (IEC), institutional review board (IRB), or both. The provision of medical treatment and the making of medical choices on behalf of subjects should always fall under the purview of a licensed doctor or dentist. Each participant in a trial should be capable of carrying out their assigned duty based on their education, training, and experience (s). Each patient should provide freely provided, fully informed consent prior to participating in a clinical experiment. Every piece of information related to a clinical trial should be handled, kept, and documented in a way that enables reliable reporting, interpretation, and verification. Records should be kept secret while adhering to the privacy and confidentiality laws as required by the relevant regulatory requirements. Investigational items should be created, handled, and stored using the best available manufacturing practices (GMP). It is important to develop systems and processes that guarantee the integrity of every part of the trial.[13]

Several legal concerns are pertinent when undertaking research. The subject's mental competence while providing informed consent is one of the key difficulties. It can be difficult to do research on people who lack mental ability, kids and teenagers, patients who are held against their will by the law, such as under the Mental Health Act, etc. During the ethical approval, this requires a comprehensive and in-depth discussion. It is crucial that researchers manage patients and study participants in accordance with the law when doing research.[14]

The Legal Procedure in Research

There are certain legal requirements for clinical studies, some of which are as follows. After seven days of learning of a major violation of the requirements and principles of GCP or the protocol pertaining to the clinical trial, the sponsor must inform the licensing authorities in writing. For the purposes of this rule, a "severe violation" is defined as "a breach that is reasonably likely to compromise the safety, bodily or mental integrity of the trial participants, or the trial's scientific value."[15]

Research Negligence

Research misconduct is a serious issue since it affects the validity of the findings and data. "The transgression of the standard rules of scholarly conduct and ethical behavior in professional scientific study" is the definition of scientific misconduct. Research misconduct comprises failing to follow established protocols if doing so results in an undue danger to people, other vertebrates, or the environment. It also includes enabling research misconduct by having others collude in or hide such misconduct.[16]

It excludes dishonesty (even egregious dishonesty) relating to the research process, as well as honest mistakes or differences in design, execution, interpretation, or judgement when assessing research techniques or outcomes. For a variety of reasons, including career pressure, publish or perish difficulties, financing, reputation, pressure to be the first to report, laziness, and ease of fabrication, people engage in scientific misconduct.[17]

Research misconduct has substantial repercussions for everyone involved, including participants, coworkers, complainants, institutions, funders, and publications. First, the validity of the research is called into doubt. The findings provide science misleading information. The applicability of the results, which can serve as the foundation for "life or death" therapeutic judgements, is put in danger. The public's confidence in the scientific industry is weakened.[18]

Types of Research Negligence

Misconduct in research can take many different forms. The fabrication, falsification, and plagiarism are the three categories of research misconduct as defined by the US National Science Foundation. Fabricating results and recording or reporting them is known as fabrication. Falsification is the modifying or omitting of data or outcomes such that the research is not correctly recorded in the research record by manipulating research tools, techniques, or materials.[19]

Plagiarism is the unwarranted use of another person's thoughts, methods, output, or words without providing due credit. It is the practice of claiming credit (or making an attempt to claim credit) for someone else's work. Citation Plagiarism is the deliberate or careless omission to provide due credit to other people or earlier researchers. It is sometimes

referred to as "citation amnesia," "the indifference syndrome," and "bibliographic neglect." It is the most prevalent form of misbehavior in science. By plagiarism, credit for a discovery may unintentionally be transferred from the original discoverer to a more well-known researcher. The "Matthew effect" refers to this phenomenon. Asim Kurjak's case was one of the most recent instances of plagiarism to be publicized; the plagiarism was discovered when scouring the literature for a meta-analysis.[20]

Self-plagiarism and the multiple publishing of the same text under several names in various publications and/or in different languages are both highly prevalent. The editors of the medical journals refer to it as "salami," which is several identical slices (MJE). Plagiarism can be challenging to spot, especially when it appears in publications with a tiny readership. Yet, there are now programmes that can detect plagiarism. Examples are CrossRef and iThenticate, among others.[21]

Giving authorship to those who have not made much of a contribution to the research is also considered research misconduct. Because of the inconsistent definitions of "authorship" and "significant contribution," this is far more difficult to show. Ghostwriting is the practice of considerable contributions being made to a work by someone other than the designated author(s). Often, this is done to hide funding from pharmaceutical firms. In addition to including plagiarism, it also contains a financial fraud component.[22]

Literally, misappropriating data refers to releasing something that makes it look as though the author did all the Labour required to get the data-that is, stealing the efforts and outcomes of others. Suppression is the failure to report major discoveries because they would be in the researcher's or their sponsor's best interests (s). The unfavorable results must also be made available to the general public and researchers in order to uphold high ethical standards.[23]

Ethics in India

Most ethical issues in research vary from approach to method. Most notably, ethics differ from one location to another. For instance, a Christian woman dressed in white denotes a bride, but a Hindu woman dressed in white denotes a widow. Most of the time, Indian cultures differ from one state to the next and sometimes even from one city to another. So, researchers should be well-versed in the cultures and other aspects of the region they are researching in.

1. The cultural variety and religiosity of India should be given top priority by Indian academics during the study.
2. They need to operate in a framework that is appropriate for various cultures, languages, castes, creeds, colors, classes, regions, etc.
3. Rather than the other way around, they must work to advance all civilizations, faiths, etc.
4. The researchers must take in mind the significant economic, educational, and technical divide among Indians when they conduct their research.

Conflict of Interest

When a person's decision about a core interest, like scientific knowledge, might be improperly affected by a secondary goal, such financial gain or personal promotion, a conflict occurs. Finding oneself in a conflict of interest is not intrinsically immoral; what is needed is to acknowledge the situation and respond appropriately. Real conflicts of interest must be considered, but so must perceived and hypothetical conflicts. Would it make me feel comfortable if people knew about or thought I had a side interest in this issue? If the response is no, the interest must be declared and properly addressed.

CONCLUSION

According to H.L.Mencken, conscience is the inner voice that alerts us when someone might be watching. For the researchers, a diligent mindset is crucial. To safeguard research participants from damage, it is crucial to uphold protocol compliance, informed consent processes, openness and integrity, confidentiality, and other standards. Professional standards of conduct and applicable legislation should always be followed.

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***Address for correspondence**
Dr. Satender Khatri
Assistant Professor,
Department of Dravyaguna,
Sanjeevani Ayurvedic Medical College, Gajraula, Amroha, Uttar Pradesh.
Email: dr.satender@yahoo.com
Mob: 9813075457