

An Overview of Ethics in Pharmaceutical Research

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Abstract

Scientific research publishing is an art and academic publishing of peer-review of journals, conference proceeding. While writing or publishing any research paper or protocol, researchers should obey a set of ethics. The present compilation provides an overview of the ethics employed in the pharmaceutical research.

Keywords: Ethics; Research; Scientific; Publication

Introduction

Research is generally defined as “studious inquiry or examination aimed at the discovery and interpretation of facts, revision of accepted theories or laws in the light of new facts, or practical application of such new or revised theories or laws”. The main objective of doing research is to extend the human knowledge beyond that is known to everybody already. The data should be prepared in such a way that research's validity can be judged independently by everyone. Only after that, an individual's knowledge enters the science domain [1].

Scientific Research Publishing is an academic publishing of peer-reviewed open-access electronic journals, conference proceedings, and scientific anthologies that distributes academic research and scholarship. A paper is an organized description or collective data of hypotheses, data and related conclusions, anticipated to educate the reader. It might not be done just as well, if your conducted research does not engender papers. It is the dissemination of one's findings to the scientific community, which are subject to peer review. Publication of research article represents the final stage of a scientific project. It is the culmination of meticulous planning of many months and sometimes years, their execution, implementation and analyses of experiments which are being conducted [2,3].

Journal editors like to publish manuscripts or papers that are being read and beneficial to the readers of the subject interest

- Papers that report “original research findings” that seems to be very “significant” are likely to be of interest to a wide range of its readers.
- Papers that are well written, organized with clearly defined statements about the relationship of findings and proper relationship of understanding/development of the interested subject.
- Papers that are briefly explained and concise in such a way that it is complete in their presentation of the research findings.

The following are examples of practices that are not punishable:

- Papers that are merely extensions of previous reports, but that do not appreciably spread fundamental knowledge or understanding in the area.
- Additive/subtractive reports of original research results.
- Fustian, below par organized papers cluttered with unnecessary illustrations that is of the poor quality.
- Violations of ethical guidelines, including plagiarism of any type or degree (of others or of oneself) [4].

Accuracy	Originality	Credit
<ul style="list-style-type: none"> • Providing complete data (not only those supporting your hypothesis) • Avoiding inappropriate manipulation of images such as photographs • Using appropriate statistical procedures 	<ul style="list-style-type: none"> • Not republishing the same findings (except under special circumstances, with the original source cited) • Not submitting the same manuscript to two or more journals at once • Not dividing one modest-sized research project into many little papers. 	<ul style="list-style-type: none"> • Not republishing the same findings (except under special circumstances, with the original source cited) • Not submitting the same manuscript to two or more journals at once • Not dividing one modest-sized research project into many little papers (“salami science”) • Observing copyright and obtaining needed permissions • Assigning authorship appropriately • Avoiding guest authors and ghost authors • If applicable, assigning contributorship • Acknowledging sources of assistance.

Table 1: Ethical Issues.

Scientific Misconduct

The Royal College of Physicians of Edinburgh discussed the current Federal definition of scientific misconduct and defined scientific misconduct (and one that is used by most universities and publishers) “as any behaviour by a researcher, whether it is intentional or not, that is unable to scrupulously esteem high scientific and ethical issues standards. Mainly research misconduct types comprise of fabrication or fabrication of data, plagiarism, self-plagiarism, problematic issues in data presentation or analyses, catastrophe to provide ethical approval by the Research Ethics Committee or to compile the individual subject’s informed consent, incongruous claims of its authorship, facsimile manuscript/publication, and don’t bother to discuss the conflict of interest”. Falsification is modification or manipulation of data or the experimental protocols to provide a required outcome so that a complicating or inexplicable result can be avoided [5].

Data Falsification and Fabrication

Data falsification and fabrication are the most common and egregious examples of scientific misconduct. "Data falsification composed of fabrication, to mislead selective reporting of research findings and inadvertence of conflicting data, or deliberately suppression and/or distortion of data". This can contain all from throwing out an undesirable piece of data to complete it. For a number of reason, falsification of data is problematic.

- First and commonly used example, it attenuates the integrity of the scientific research, both from that original author(s) and from others in the field who read it.

- Second, if left undiscovered, it is again just wastage of researcher’s time, efforts and money attempting to duplicate or generate on the data presented in that falsified paper.
- Third and last example, it endangers the interest of public trust in the scientific enterprise and its related activities.

While writing any research proposal/conclusions, researcher should not fabricate data, because falsification can leads to erroneous results or conclusions that may further effect the adverse consequences for patients in the clinical practice and research". If an investigator was to fabricate research findings for their own sake of interest only on a paradigm shifting disease management program and a potentially new clinical therapy, the impression on a patient/subject could be life threatening at the nastiest and psychologically devastating at a minimum [5,6].

Plagiarism

Plagiarism can be defined as the mugging or embezzlement of intellectual property.” or “the substantial unattributed textual copying of another’s work. The stealing or misuse of intellectual property right comprises of unauthorized usage of ideas or exclusive methods acquired by a fortunate communication, such as a perspective, manuscript review or grant. Generous textual copying of another’s work means the unattributed verbatim or nearly verbatim copying of sentences or paragraphs which materially mislead the ordinary reader regarding the contributions of the author” [7]. Objectively:

- Plagiarism: is the process by which the researcher have used the ideas or words of another researcher or person without giving an appropriate credit (Nat. Acad. Press document)

Dr. Mark Wiser of Tulane University (New Orleans, LA) has evaluated the seriousness of plagiarism allegations and suggested the five criteria that were to follow. The five criteria are given as:

- 1) What was the main extent of the plagiarism?
- 2) Was the intent of subject vicious?
- 3) Has the researcher or author engaged earlier in plagiarism?
- 4) What is the designation and training of the author of the subject? And
- 5) Was the source of the study material original or have the plagiarism occurred from the other notes?

Intentional	Unintentional
<ul style="list-style-type: none"> • Copying a colleagues' work • Purchasing or stealing papers of the subject • Acerbic and drubbing of text from electronic sources without giving credits • Media "deriving" without certification • Network publishing without having permissions of creators. 	<ul style="list-style-type: none"> • Careless paraphrasing • Poor documentation • Quoting excessively • Failure to use your own "voice"

Table 2: Types of plagiarism.

Plagiarism can be:

1) Plagiarism of Words

- Plagiarism is defined as the process by which the author uses exact words of another's without citing the author
 - Incorrect: It is termed as the replica of someone else's words, ideas or research findings and presenting their data as one's own without giving the proper acknowledgement.
 - Correct: It is defined as the "imitation of someone else's disagreements, ideas or verdicts and presenting them as one's own without proper acknowledgement".

2) Plagiarism of Structure

- Paraphrasing another's words by changing sentence construction or word choice with citation
- Paraphrasing while maintaining original sentence construction with acknowledging the source

3) Plagiarism of Ideas

- Ideas can be plagiarized by presenting another author's side as your own without providing the person credit
- Publishing a paper without mentioning or imperfectly citing another's ideas

4) Plagiarism of Authorship

- Whirling in a imitation of another person's work
- Communicating a paper that you acquired off the internet or from a colleague or friend and presenting it as your own

5) Plagiarism of Self

- The use of earlier work for a detached assignment
- Although these were original words and thoughts you write, receiving credit for a preceding assignment is deliberated cheating.

Nowadays, the trend in the regulatory protocols scheme of dealing with plagiarism is inconsistent among scientific journals. Educating the graduate students, post-graduate students, postdoctoral fellows, and faculty is mandatory to follow some a set standard of scientific research conduct of the particular interest. Dr. Miguel Roig, St. Johns University (New York, NY), has extended a complete and thorough set of guidelines about the finer points of plagiarism and writing some practices that may not pass ethical muster [8]. These underlying guidelines are given as the following:

- 1) The originator of ideas and the contribution of another should be acknowledged explicitly always, regardless of whether it was summarized, abridged, or used directly;
- 2) Enclose any verbatim text occupied from another author in quotation marks [6,8];
- 3) While paraphrasing, you should understand completely the text and use your own words in that paragraph; and

- 4) The references should be provided when you are not sure about that fact or idea you are by means of his common knowledge.

There are few numbers of different types of computer programs accessible to detect commonality of language between different written works [8,9].

Prevention of Plagiarism

- Develop a topic based on previously written material but write something new and original
- Rely on opinions of experts on a topic but improve upon those opinions
- Give credit to researchers while making your own contribution
- Follow a standard documentation method such as MLA or APA format [10].

Redundant Publication

Redundant publications is termed as a special type of plagiarism. It is sometimes associated with the replication or duplication of the publication. The repetitive or redundant publication is defined as the publication of the copyrighted material with additional novel and unpublished data. Therefore, in the other words, we can say that redundant publication is the republishing of a part or some parts of an already published paper or article, but not the entire article. There are a number of case studies that why redundant publication is unethical. The underlying reasons are therefore elaborated:

- First, it may infringe international copyright law.
- Second and foremost important, duplication or replication of data with additional newer data wastes the valuable time and energies of expert peer reviewers.
- Third, it unnecessarily increases the extensive body of already published literature.
- Fourth, it misperceived the scientific communication of the subject interest by merely dividing rather than combining closely related data from a single study group.
- Fifth, it may overly exaggerate the significance of the research findings by taking them seem as more than once.
- Sixth last but not least, it may interfere with subsequent study and meta-analysis by apparently advancing patient or experimental numbers.

Duplicate Publication or Self-Plagiarism

Duplicate publication is considered as the publication of a manuscript and an article that is identical, unique or overlaps substantially with an article that is already published elsewhere, with or without acknowledgment. It can be therefore, classified as self-plagiarism. It is defined as a subset or a particular set of redundant publication in that two papers share the same hypothesis, results, and conclusions. Why do the research scientists endeavored to republish the same article? One reason that is very common may be the perception that to endure in the highly competitive biomedical science and pharmacy field, individuals researcher or authors are mandatory to achieve voluminous curriculum vitae. Another one most important reason, at least before the initiation of the world wide web, is the authors wish to scope readers that would not certainly be acquainted with the particular journal in which the article was first published (for example, if the research article or review was published in Chinese in a relatively inaccessible journal).

Why replication of the publication is considered misconduct? Besides, the obvious attempt to expand one's own publication or research record, redundant and duplication of publication has the potential to twist the evidence base. If the same research data or findings were counted twice (or more), the outcomes of meta-analysis used to provide the best practice would be invalid. Duplication of publication is a menace for scientists conducting the systematic reviews and, more importantly, biases the conclusions on drug effectiveness and safety [10,11].

Authorship Issues

Every scientist has his/her own idea and conception of what is essential to be an author. Though, often these ideas diverge among participants in a particular research project. Disputes and behavior conflicts can ascend during an investigation that may cause disharmony and disparity over who qualifies for authorship. There are several general guidelines put forth by the entities such as the National Institute of Health and The Council of Science Editors for settling of authorship issues. "The credit of authorship should be based on:

- 1) Substantial assistances to conception and design of the experiment, or acquisition of data, or analysis and interpretation of data;
- 2) Drafting the manuscript or article or revising it critically for important intellectual content; and

- 3) Approval of the final version to be published. An author should meet the above mentioned conditions 1, 2, and 3".

International Guidelines for Ethical Conduct in Scientific Publishing

In order to provide a common international reference for ethical behaviour in scientific publishing, as well as to suggest appropriate responses to misconduct when it occurs, the following guidelines are proposed for the various parties in the scientific publication enterprise. It is important to consider that it is not unethical to be wrong, provided that errors are promptly corrected.

Institutions

The senior management of a university or research institution should set high standards for ethical behaviour, including all aspects of research publication, and should actively post and promote these to employees. Institutions should establish research practices that minimize the possibility of misconduct and also protect the rights of younger researchers. Regular instruction in ethical behaviour should be provided to employees. Institutions should also establish procedures for objective investigation in the event of accusations of misconduct and outline penalties in the event of a positive finding.

Individual Researchers

Individual researchers should appreciate and scrupulously uphold the high standards for ethical behaviour in the conduct of study research, particularly with the relationship to the verification and truthful reporting of data, the granting of proper credit, and citing or referencing of the work of others in publication.

- Plagiarism of another author's work is a form of mugging and it constitutes serious misconduct. Individual researchers should ensure that institutional guidelines on ethics are known and upheld, and they should promptly raise and resolve as appropriate any misconduct that may occur.
- In publication it is necessary that each co-author contributed significantly to the study of research reported and openly accepts joint responsibility for the work of that subject. If these specified conditions cannot be met, the person should not be included as an author in that paper.
- Concurrent submission of an article relating the same research to more than one publication establishes the misconduct because it delays editorial and referee time for the author's own purposes.
- With the same line of thought, publishing the same results in more than one primary research journal or proceedings is a form of misconduct and is not acceptable. Exceptions are made by some journals for previous publication in conference proceedings.

- At submission, an author is bound to disclose any prior appearance of the work so that the journal may make an informed decision about whether to accept it for peer review.

Journals

The team of scientific journals and senior management should be established to post their quality standards for ethical behaviour in posting, publishing. Their responsibilities and steps should be specified in investigating and responding to suspicions or accusations of misconduct. Journal managers should ensure that these standards are as clearly understood and upheld internally as they are externally.

- Journals should respond to author complaints with respect and due process but also keep community needs in mind in apportioning resources.
- Journals should work closely and responsively together to resolve inter-journal problems such as plagiarism or duplicate publication. As far as is possible within the publication structure,
- Journal management may establish private and public penalties for those found to have committed misconduct, be they authors, referees or editors.

Editors

Editors should follow to high standards of ethical treatment of all authors in arriving at a particular responsible and objective decision about publication. An editor will excuse himself or herself from editorial duties that would impose a personal, financial or professional conflict of interest. An editor should obey the editorial policies and duties to impact the handling of their own papers or those of colleagues or rivals. They should also avoid any misuse of their privileged position or information.

Referees

Referees should adhere to high standards of ethical treatment of all authors in arriving at a responsible and objective recommendation about publication. A referee will excuse himself or herself from refereeing duties that would impose a personal, financial or professional conflict of interest, and will avoid the use of privileged information in a paper under review.

Professional Organizations

National and international professional organizations shall take a leadership position in establishing and stating standards of ethical conduct, developing these standards in consultation with membership, specialist committees and governing bodies. These standards should be well publicized and prominently

posted. In addition, standards should be examined regularly and revised to cover appropriate publishing practice and any new situations as they arise [12].

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