



71. Ethical rules in scientific publications

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Background

The public recently became aware of an unfortunate and embarrassing case in which a research article was accepted for publication despite the fact that the research had apparently never been conducted. When the authors of the article were asked to assume responsibility for its contents, one of the authors, a department head, replied that he did not know what they were talking about. According to him, while standing in the lobby during a professional conference, he gave his written and signed consent to the publication without bothering to check what he was committing himself to and without actually taking any part in the work.

This was the sad climax of a sorry, ongoing reality that is further reflected in complaints received by the Ethics Board, whereby the list of authors of scientific articles does not always reflect their actual contribution. This is an expression of the tradition in which the department head is always regarded as the author of an article in any work published from his department, even if he took no part in it.

The editors of leading medical journals throughout the world are now conducting a very important campaign intended to preserve public trust in the scientific truth published in these journals. The boundaries of the struggle go beyond the framework of this position paper, but in order to protect the status of medicine in Israel, we saw fit to reiterate to physicians in Israel what is and what is not proper in scientific publication.

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a) General introduction

All those who engage in scientific and medical research are obligated to absolute intellectual integrity. This integrity is intended to preserve the rectitude of the research and its professional standard on the one hand, and to preserve the trust of the public in the scientific information published, on the other hand.

This basic obligation has made the status of an author in a scientific publication in the current culture especially sensitive. The status of "author" has become a major tool by means of which the researcher's professional and academic capability is judged. The number of articles published currently determines the status of the researcher in the scientific medical community to which he belongs, serves as a major tool in his progress up the university ladder, and constitutes virtually the sole measurement tool for awarding research grants and the salary derived from them.



The change that has taken place in the current nature of research, which obligates cooperation between large and numerous research groups, has also led to numerous difficulties in determination of the location of each "author" in the long list of names of all the participants in the research.

The status of an "author" is not a gift from heaven. It expresses scientific and social responsibility that the author takes upon himself. Besides the professional credit and the social recognition, this status also contains a commitment to take responsibility when things don't work out properly, such as when the information furnished transpires to be incorrect; when the findings cannot be repeated; or when the conclusions presented are found to be exaggerated and unsubstantiated. Consequently, the status of "author" grants great honor together with great responsibility. Medical research requires tremendous investments, most of which come from the pharmaceuticals industry. This industry has its own agenda that does not necessarily correspond to that of the research physician. In this bitter reality, several cases have unfortunately been recorded in which commercial and economic considerations of the entity financing the research have taken precedence over the scientific truth and have led to the distortion or concealment of medical information from the public, so as to serve the needs of the financing entity. An urgent need has arisen to redefine the reciprocal relations between the medical academia and the pharmaceutical industry, to preserve the academic freedom of the researcher.

The ethical code appearing in this document is intended to solve some of the problems. This is not a complete document, and it addresses a limited number of subjects related to medical articles. In our opinion, it will be necessary to complete and revise it in the future, and to adapt it to the changing reality.

We suggest that all the readers examine the appendix "Uniform instructions for the publication of articles in bio-medical journals". This important document was first published by a group of editors of bio-medical journals originally called "the Vancouver Group", which, over the course of time, became the international committee of bio-medical journals editors (ICMJE).

In recent years, this committee has published a number of revisions to its basic document. The latest version, written in October 2004, appears on the website: www.icmje.org.

b) Authors of a scientific-medical article

The definition of an "author" of a medical article is now clear and has been well defined by the international committee of bio-medical journals (ICMJE).

According to this definition, a person shall be regarded as an "author" if he meets the following conditions:

1. He made a real contribution to the conception or planning of the basic idea on which the research is based, to analysis of the results or to the giving of significance to or interpretation of these results.



2. He wrote the article or introduced material changes into it, while adding new, genuine intellectual content.
3. He gave final approval of the article for publication.
4. In cases of multi-center research with many researchers, the researchers must choose from amongst themselves those directly responsible for the published work. These researchers must themselves meet the definition of "author" in accordance with the aforesaid agreed criteria.
5. The mere provision of financial support, the simple collection of information or samples, or "general supervision", do not themselves award the right to the status of "author".
6. Each of the authors of an article must be a real participant in a substantial part of the research, so that he can face up to criticism by his professional colleagues and by the public of material parts of the scientific publication.

These rules clarify that the status of an "author" cannot be a gift or honor awarded to a specific person by virtue of his position only. For example, it is improper to offer the status of "author" to a department head only because he is the head, if he made no material contribution to the research as set forth above.

The order of appearance of the authors in the research article must be determined in advance and with the agreement of all the researchers. It is customary that the author whose contribution to the research was the greatest and most decisive should appear at the head of the list. Next will appear the author whose contribution was second in value, and so on. It is customary that the last author in the list is the senior researcher, in whose laboratory or under whose direct supervision the research work was conducted. The last author of the article must also meet the criteria of "author" as set forth above. The status of the last author must not be awarded as a gift or honor for the said person.

1. Every author must carefully read the entire article, before its publication, and agree both with the form and contents of his own part and with the parts of the other authors.
2. No article shall be sent for publication without the criticism and agreement of all the authors.
3. Every author is personally responsible for the contents and conclusions of the entire article. Every author must be prepared to defend the contents of the article published in his name, including both his part and that of his colleagues in the article.
4. All other participants in the work, whose contribution to it does not reach the level of "author", shall be referred to separately in the acknowledgements.
5. The authors shall briefly indicate the contribution of each author on a special form, to be attached to the article at the time of its submission to the editors of the journal. This shall appear in a footnote to the article.



6. No researcher shall permit his name to appear as the author of an article unless he meets the required conditions as set forth above.

c) Duplicate (redundant) and salami publications

- Duplicate publication –the repeated publication of an article, which clearly overlaps a previous article already published. Such overlapping may occur when there is a clear-cut resemblance to the fundamental hypothesis on which the research is based, the characterization of the sample, the identity of the patients, the research methods, the results of the research or its conclusions.
- Salami publication – the slicing up of data received from a single research and dispersing them in several different journals or on different dates, with the intention of increasing the number of articles.

Duplicate and salami publications damage and distort scientific truth and are consequently prohibited.

The damage caused by these publications is very great. It is sufficient to cite the waste of resources caused by publication at the expense of other original articles, the waste of time of the reviewers of these articles and the creation of an artificial load of information that has no proper purpose. It is also important to note that duplicate publication is liable to lead to medical bias in meta-analysis of evidence-based medicine.

Furthermore, publications of this kind frequently involve legal problems of copyright theft. Worst of all, such articles permit misguided academic advancement because of apparent "achievements".

The authors shall declare that the article submitted for publication is original and has not been submitted in parallel for publication in another journal, and that the relevant information has not already been published somewhere else.

Duplicate or salami publication is permitted in the following cases:

In large-scale epidemiological or clinical research, whose results cannot be published at that time, or that address difficult research questions.

In a previous publication of the research as part of an abstract submitted for a scientific conference, provided that the editor of the journal is aware of the previous publication.

In a duplicate publication in different languages intended for different readers and with the knowledge of the editors.

d) Conflicts of interest

The trust of the medical community in particular and of the wider public in general regarding the truthfulness of medical research obligates transparency and clear knowledge that the information published is free of any overt or covert bias, and that those who conducted the research were free of any conflicts of interest.

A conflict of interest exists when the "author" of the article, the institution in which he



works, or the "reviewer" of the article have personal interests liable to influence the results of their scientific work. Such a conflict of interest is also liable to exist when the "author" or the "reviewer" are convinced that such a conflict will not influence their scientific judgment.

Reciprocal financial relations are the major reason for a conflict of interests in medical research. This includes employer-employee relations, especially in the case of a pharmaceutical or hi-tech company, which holds shares or securities of a commercial company that has an interest in the results of the research, the receipt of "consulting fees" or financial remuneration for lectures made on behalf of the said commercial entity involved in the research, etc.

A conflict of interests is also liable to exist in other circumstances, including the existence of personal relations with other researchers, academic competition, and intense emotional involvement in the research.

The absence of integrity and transparency in the medical information published will necessarily lead to lack of trust towards the researchers, the journal publishing the article, and medicine in general.

Consequently, every researcher who publishes a medical article must fully and honestly reveal and expose every possible conflict of interest that may influence his judgment. This directive applies both to reviewers of medical articles and to the writers of editorials in medical journals.

e) The academic independence of the researcher

A significant part of medical research is currently conducted with the direct financing of commercial companies. This form of financing has a dangerous potential to bias the results of the research in accordance with the economic interests of the entity financing the research.

In order to preserve the academic independence of the medical research and its status in the eyes of the general public, the ICMJE has recently issued stricter instructions, according to which the researchers must avoid signing research contracts which contain any restriction whatsoever regarding the absolute freedom of the researchers when conducting the research.

In accordance with the new instructions, every researcher who contacts a journal with a request to publish research must declare that he had full access to all the information collected in the research. In addition, he must declare that he was able to independently process the information collected, that he was given full freedom to write and publish the article, even if its results do not fulfill the expectations of the entity financing the research and that he bears personal responsibility for the accuracy of the information published. The head researcher is also required to specify the part of the entity financing the research, if any, in these processes.



This declaration by the researcher regarding full academic freedom is now routinely required in every article submitted for publication, together with a declaration regarding a possible conflict of interests, as set forth above.

In order to prevent concealment from the public of "negative" medical information for the entity financing the research, the editors of the journals decided that beginning July 2005, prior registration of every clinical trial would be required as a necessary condition for its publication in the future. Registration shall be done via a digital website, accessible to the public at no charge. The website shall contain, inter alia, information related to the identity of the illness that forms the basis for the research, the nature of the treatment being tested, and the aims, scope, and identity of the commercial entity financing the trial.

The address of the website in Israel is www.clinicaltrials.gov.il.

In September 2005, the Ministry of Health published a Director-General circular that lists the instructions for registration of medical trials in the database. The researchers must comply with these instructions.

f) Afterword

Researchers should constantly be cognizant of the great responsibility they bear. They must remember that their fellow physicians who read the article before treating patients will use their work. Consequently, they are obligated to write every word, to consider every sentence, with the maximum possible caution and with the same degree of concern and caution as if they themselves were treating a patient at that very same moment.

With that same ethical commitment, they must fulfill this important duty with full scientific accuracy, and with intellectual and personal integrity.