

## Clinical Research Authorships: Ethics and Problem-Solving

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### Résumé de l'article

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COMMENTAIRE CRITIQUE / CRITICAL COMMENTARY (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

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Atif A. Katib<sup>a</sup>

### Résumé

L'article aide à résoudre la question complexe de la paternité des œuvres en se basant sur les réglementations des organisations mondiales. Il établit une distinction précise entre la paternité et la contribution du point de vue de l'éthique de la recherche.

### Mots-clés

autorat, recherche clinique, contribution, remerciement, résolution de problèmes

### Abstract

The article helps resolve the intricate authorship issue based on global organizations' regulations. It draws a fine line between authorship and contributorship from the research ethics perspective.

### Keywords

authorship, clinical research, contributorship, acknowledgement, problem-solving

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## INTRODUCTION

Between about 1980-2010 the average number of authors in medical papers increased and perhaps tripled (1). An increasing number of researchers and graduates are chasing publication opportunities under the pressure of “publish or perish” (2,3). Publication has become a prerequisite to graduate, to find a post, to apply for a scholarship, to be promoted academically, and even to keep one's position. In academia, sometimes, researchers are defined by the magnitude of publications to which they have contributed (4). Universities and research institutions are more likely to recruit and promote those academics carrying voluminous résumés with a larger number of published articles (5).

The fields of research and publication are more feverish than ever. Usually, research evolves from a cordial collaborative effort between associates with all intending to bring forward a decent scientific paper that is good for publication. At this point, the research team should meet face-to-face to discuss openly who will be the first author, the order of co-authors, and contributors; based on the relative contribution to the research and the accountability to be held (Figure 1). All the parties involved need to agree on the author list before submission, and no one, in good faith, wants to delay submission because of a disagreement about who should be on the author list and in what order.

Figure 1. Authorship equation



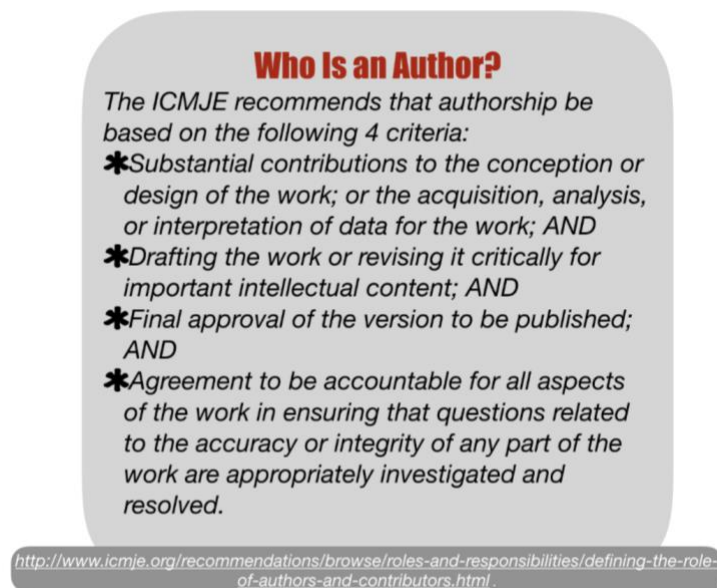
Researchers should familiarize themselves with proper authorship practices in order to protect their copyrights from research fraud. Moreover, researchers should be aware of the authorship practices within their own disciplines and should always abide by the requirements stipulated by a prospective publishing journal. As some journals require processing and/or publication fees, financial issues should be settled and agreed upon early in the research process to avert subsequent disputes. The Committee on Publication Ethics (COPE) has a guide to help researchers navigate authorship issues (6). Detailed management of authorship disputes is beyond the scope of this article.

## AUTHORSHIP IN BIOMEDICINE

In general, an “author” is someone who has made substantive intellectual contributions to a published study (7). Typically, an author is a creative person who has the gift to come forward with an innovative plan or idea (8,9). In addition to editorial guidelines, academic organizations in different fields have their own criteria to define and consider suitability for authorship.

Unlike other disciplines, the medical field defines authorship very narrowly. According to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals that have been revised by the International Committee of Medical Journal Editors (ICMJE), there are four criteria that each author on a paper should meet (Figure 2) (10). Several journals refer to these criteria in their own policies, particularly in the “author guidelines” section. The criteria indicate that each author of a paper should be involved in the design, data collection, analysis, or interpretation of the data. Moreover, all authors should be involved in writing or revising the manuscript, approving the final draft, and be held accountable for the accuracy and integrity of the work (11).

Figure 2. ICMJE criteria for authorship



Acquisition of funding, administrative support, writing assistance, technical editing, language editing, proofreading, graphic designing, or general supervision of the research group do not constitute authorship and are not recognized ethically as “author tasks” (12). Such contributors should be acknowledged at the end of the manuscript.

Notably, many junior doctors begin their writing career by authoring a “case report” as the first step in building a track record of publications. Mentors have to bring authorship protocols to their attention not to add on irrelevant colleagues.

## CONTRIBUTORSHIP STATEMENT (CS)

In cases where articles are authored by several individuals, i.e., “multiple authorship”, each one has to specify their role honestly and sign off on their precise contribution. CS does not only assign every part of the work to the person who carried out the task; it helps to also identify a contributor if things went wrong. For example, if the peer review process flagged issues with the data, the CS makes it easier to identify the person who shared the questionable data. In addition, as this trend of multiple authorship continues, grant and tenure committees should request clarification of publication claims, that is, when such a statement would help delineate precisely who did what. Similarly, acknowledged contributors have to elaborate their inputs, as that limits their responsibilities to the declared contributions.

## WHAT IS GHOST, GUEST, GIFT, AND HONORARY AUTHORSHIP IN RESEARCH?

An “author” is a creative person whose intention is to circulate original ideas and intellectual works. In scholarly publishing, the role of the author carries significant responsibility, legal rights, and privileges. The career of academics is often based on the authorship of the papers published by them. In some situations, it exerts tremendous pressure on the academics to publish, a matter that has been blamed for inciting them to commit scientific fraud and research misconduct (13).

Some academics lack proper writing skills, yet they wish to retain their jobs. For this reason and many others, they resort to different ruses (14). The Council of Scientific Editors (CSE) describes a range of inappropriate authorships including “guest” authorship, “honorary,” or “gift” authorship, “ghost” authorship, and “anonymous” authorship. As authors are expected to take public responsibility for the article and its content, scientists should not publish their scientific reports under pseudonyms or in an anonymous manner. The CSE states that journal editors may allow for anonymous reports only when the author fears that revealing their identity could threaten their life or lead to loss of livelihood (15).

The corresponding author is not necessarily the most senior author or project lead. Their responsibility is to establish appropriate liaison between the research team and the editorial board of the relevant journals. Typically, they respond to all manuscript queries and follow up the submission until publication (16). Common dishonest authorships are:

### The guest

According to the guidelines by the ICMJE, guest authors are indirectly affiliated to a study article. CSE describes “Guest” authorship as the one that is bestowed upon individuals who are only tangentially involved with the research project. However, it is not uncommon in academia for researchers to turn to this tactic in a bid to acquire grants, funds, or loans. Lead authors sometimes find themselves obliged to include their supervisors in a publication, despite the lack of direct contribution. At some institutions, this questionable practice is legalized as a “passive contribution”, although this remains an exception, not the rule (17). In general, guest authorship is an unethical practice; this explains why most journals resort to the contributorship statements to avert this act.

### The gift or honorary author

Over the years, surveys have estimated the prevalence of gift/honorary authorship to be at 11-60% (18-21). Articles with over five authors are more likely to have “honorary authors” than those with three or fewer number of authors (22). Colleagues with lower academic rank or those with fewer publications, a supportive mentor, head of a department, or a facility manager are common examples of gift authorships. To put it clearly, unless they were an active part of the research process and the manuscript creation, they should not appear on the author list (21). This practice is believed to be primarily responsible for the over inflation in the number of authors per article in biomedical journals (23,24).

Adhering to current author guidelines, “gifts” may become obsolete. The degree to which the workload is apportioned can depend on rank, experience, and expertise. Some contributors would be granted a place on the team solely based on rank, with the hope that when their names show on the author list, it would improve the team’s chances of getting accepted for publication in a prestigious journal (25). Others could be “invited” because they authored the original study design or provided the dataset for the study. It is of utmost importance to discriminate between legal and illegal “invited authors”. Some prestigious journals do not accept submitted manuscripts. Instead, they solicit the input of world-class scientists to write on special subjects. In this case, the writer is virtually an “honor author” who does the writing job themselves. Therefore, this practice of “inviting” eminent writers is legal from the authorship viewpoint.

### The ghost

The ghost-writer is, typically, a professional writer who contributes to the major part, in not all, of the work to produce a paper but is not named or disclosed in the author byline or acknowledgments (26). Those writers often work for medical communication agencies commissioned by pharmaceutical companies and ensure timely publication of large clinical trials. Such writers are compensated monetarily. In a similar vein, junior colleagues, postgraduate students, postdoctoral fellows, or junior researchers could be ghost authors. This vulnerable category of researchers is recompensed in many different ways. The named authors who conducted the research might not have written the article themselves. Therefore, they do not meet the ICMJE criteria for authorship. Ghost authorship is not uncommon in journals reporting large-scale clinical trials, regulatory documentation, and literature summaries for healthcare professionals.

Scams in the medical writing industry have gone awfully far; from an underground “academic bazaar” where authorship can be brought to the paper’s content being dictated (27). Ghostwriting, which was a “dirty little secret” of the medical literature, has now grown to be a full-fledged industry of its own (28). Gøtzsche et al. found that 75% of industry-sponsored trials were ghost-written, as they did not include the names of individuals who wrote the protocol, analyzed the study findings, or wrote the manuscript. The ghost authorship industry could even have marketed several drugs (29,30). The National Association of Science Writers (31) and the American Medical Writers Association (32) now regularly update guidance for medical writers. The European Medical Writers Association has similarly developed guidelines for ghost authorship in peer-reviewed publications (33). These guidelines require the lead author to generate the content, to fill in the funding statement, to compose the title page, and to acknowledge the involvement of professional writers (34). The World Association of Medical Editors (WAME) considers the phenomenon of ghostwriting as dishonest and unacceptable (35). Ghostwriting bestows undeserved credibility to the paper that has been written by a person possibly employed by a pharmaceutical or medical device company (36). Many readers could be deceived to perceive it as an unbiased article written by an academic. This deception in the author list does not allow the discerning reader to assess the impact of bias in published research (28).

### WHOSE NAME SHOULD BE FIRST?

Although single authors wrote the vast majority (>98%) of important medical articles a century ago, this has become a rarity; less than 5% are now single-authored. Too many authors spoil the credit (37). Meanwhile, the number of multi-authored articles has escalated, many of which list individuals who made insignificant contributions. Over the last couple of decades, the author list has been notably expanding. Among biomedical publications indexed in MEDLINE/PubMed, the average list of authors on a paper doubled from 3 to 6 since the 1980s (38). At times, the list of authors reaches astronomical numbers, occupying as much space as the corresponding abstract. Extreme examples include a report in the physical sciences on high energy physics

with an article with more than 5,000 authors (39), the Large Hadron Collider listing almost 3,000 authors, and a clinical trial published in *The New England Journal of Medicine* listing 974 authors (40).

To the extent that the author list reflects those who have made substantial contributions to a research project, the author order should not matter. In theory, everyone on the list should be credited equally as the project was the result of teamwork. In real life, listing of authors often does not go that smooth since some authors will be more visible than others. The “first author” is a coveted position because of the increased visibility. On account of various citation rules, such as MLA referencing style, the first author may be the only name to appear and would be the public name of the whole project. In-text or bibliographic referencing rules could reduce all names down to only the first one, e.g., “Adam et al” (41).

In several fields, the last slot is reserved for the group leader in charge of the project, whereas in others, the last author is the corresponding author. In many disciplines, such as the life sciences, the last author is reserved for the person who supervised the work.

## COMMON METHODS FOR LISTING AUTHORS

“Relative contribution”: The author who most substantially worked on the draft article and the underlying research becomes the first author. The others are ranked in descending order of contribution.

“Alphabetical list”: Certain fields, particularly those involving large group projects, employ other methods. For example, high-energy particle physics teams list authors alphabetically.

“Negotiated order”: In spite of the fact that there are ways to determine first and last authors, there is no general agreement for the middle authors. The list can be decided by negotiation only (42).

In situations where two people have contributed equally to the work, it is becoming more common for authors to assign a co-first author for their paper. This is often indicated with an asterisk to mark which authors are meant to be equal. Although this practice is common in interdisciplinary studies the first name listed on a paper will still enjoy more visibility than any other “first” authors.

## Example scenarios and issue resolution

### *Problem I: authorship and contributorship*

Sofia is a graduate student working under the supervision of Dr. Rajab who is conducting research on the management of heat exhaustion in tropical countries. Sofia has collected data from Dr. Rajab’s files; yet, she came up with a research question on her own, about improving the hydraulic system of the cooling beds for heat exhaustion sufferers. Sofia’s friend Philip has helped her design statistical computer software for data analysis but did not contribute in any other way to the research. When writing the research results, Dr. Rajab helped Sofia write the methods section of the manuscript, reviewed the results and conclusion, and approved the final draft of the manuscript.

*Query:* how should authorship order be judged in this scenario?

*Answer:* Sofia should be listed first as she is the most closely involved person in the research work. Dr. Rajab should be listed second as he meets the ICMJE criteria for authorship. Philip should be only acknowledged as his contribution is a non-author task.

### *Problem II: contribution statement*

Fuji and Abdu are post-doctoral fellows who are finalizing a research draft. When Fuji knew that his contribution would be ethically categorized as a non-author task and subsequently, he would not be entitled to authorship, he backed out and left the project. The section head put the research on hold until the issue could be resolved.

*Query:* how to manage the situation?

*Answer:* at the contribution statement, some publishing houses require authors as well as contributors to sign against the role they played. Therefore, Fuji has to sign the contribution statement at the acknowledgment corner. If he refused to do so, it would be a good idea for the section head to require Fuji to sign a waiver letter and save it in the research file. However, the manuscript with Abdu’s name only should proceed for publication undeterred.

### *Problem III: Ghost, guest, and lead authorship*

Rashidov is an active junior researcher who works with his senior, Mariam, on a research of her own idea as to how to demonstrate first aid nonverbally. He offered to communicate with the actors, journal editors, and the publication house. He did some data mining and reviewed the final draft of the manuscript. Although Mariam has contributed by conducting the motherload of the research, she is uncomfortable being held accountable for the project. Patrick, the division chief, is a prolific writer who has generally supervised the work and helped in fund acquisition and wished them the best. On submitting the manuscript to the journal, Rashidov listed the authors in this sequence: Patrick, Mariam, Rashidov.



**Query:** What is the proper description of every contributor based on his or her role? What, ethically, should the author list look like?

**Answer:** Patrick is a guest author as he contributed to the work by non-author tasks. His name was listed to support the research for the editorial board of the journal and its readership. Mariam contributed substantially and the research idea was hers; however, she is not an author by the ICMJE criteria as she does not agree to be accountable for the manuscript. Rashidov is the corresponding author as he manages the communications needed to publish the research.

As ghost authorship is not ethical, Patrick should be offered an acknowledgment at the end of the manuscript. Mariam should be omitted from the whole work. Rashidov will be left as a single author.

## CONCLUSION

The ICMJE four criteria of authorship determine who is ethically an author. Contributors who do not meet these criteria are acknowledged at the end of the manuscript. There are common dishonest ways to earn authorship, though the responsible filling in of the contribution statement form has helped limit this malpractice. There are several methods by which authors are ordered. The commonest is based on the relative contribution of each in a descending fashion.

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Aucun à déclarer

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### Conflicts of Interest

None to declare

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