

*Viewpoint***The new ICMJE disclosure form**

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Abstract

Effective 30 June 2021, the International Committee of Medical Journal Editors, ICMJE, has updated its [disclosure form](#). It is now public on [ICMJE's web page](#), and member journals have started using the form. In the ICMJE, editors of general medical journals discuss and adopt proposals to address important problems in medical publishing, such as authorship definition, trial registration, data sharing, and the declaration of conflict of interest. All of ICMJE's proposals are summarized in the "[Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals](#)", a 19-page document containing advice on a wide variety of topics related to manuscript writing and publishing.

Keywords:

COI, conflict of interest, disclosure form, ICMJE

Effective 30 June 2021, the International Committee of Medical Journal Editors, ICMJE, has updated its [disclosure form](#).¹ It is now public on [ICMJE's web page](#), and member journals have started using the form. In the ICMJE, editors of general medical journals discuss and adopt proposals to address important problems in medical publishing, such as authorship definition, trial registration, data sharing, and the declaration of conflict of interest. All of ICMJE's proposals are summarized in the "[Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals](#)", a 19-page document containing advice on a wide variety of topics related to manuscript writing and publishing.

The new disclosure form was born out of a combination of technical necessity – the old form was no longer compatible with some web browsers – and the need to adapt the content after the form had been in use for more than a decade. The update has been developed in discussions within the ICMJE, but it also owes a lot to input from the field that the ICMJE requested, with an editorial and a tentative form published in January 2020. In total, more than 100 individuals and groups provided feedback.

The current form is new in two important ways.

1. The loaded term 'conflict of interest' has been abandoned because many authors and editors felt it was too negative an expression. When what has to be described – paid membership on an advisory board or study support by the industry, for example – is not inherently a bad thing, critics argued, the descriptive term should not

be negative either. Changing from 'conflicts of interest' to 'relationships and interests' also aims at lowering the psychological threshold for declaring, thereby reducing the number of false-negative statements.

The downside may be the unspecificity of the new expression 'relationships and interests' and the loss of a descriptive term that replaces 'conflict of interest'. It seems therefore possible that the expression 'conflict of interest' will prevail, for example in medico-political debates or in research on the topic. At the same time, readers are unlikely to misunderstand the new term because, by now, it should be well established in medicine that cooperation with the industry may come at the cost of bias. If the new term indeed brings more authors closer to full disclosure, the change can be considered a success.

2. The new form also aims to be unequivocal in exactly what relationships and interests that need to be disclosed: it lists 13 areas of relationships and interests that specifically need disclosure. This change is an attempt to relieve authors from the burden of deciding by themselves what has to be named. In being more specific about the relationships and interests that should be named, it is also hoped that there will be fewer contradictions among declarations by different authors who follow the same practice, for example all those on a speakers' bureau of a given pharmaceutical company. The new form lists more than 30 examples,

and an additional open question allows rare or hitherto unknown relationships and interests to be included. It is also possible to declare non-financial relationships and interests, which remain an elusive concept and will continue to cause difficulties; for example, some authors may consider their membership of a school of thought an interest whereas other authors who belong to the same school might not.

Rather than a chore, filling out the ICMJE disclosure form should be seen as a positive act that will strengthen trust in science: by disclosing their interests and relationships, authors show that they are committed to transparency.

The disclosure form retains the distinction between support for a study that is being presented – to be declared no matter how far back in the past it was received – and all other interests and relationships for which there is a 36-month time frame. This period of 36 months from the date of submission represents a trade-off between what can be remembered with reasonable certainty and what interests and relationships may still exert an influence on authors and may lead to bias. It should be noted that the form is about disclosing not only large-scale relationships between authors and partners in the industry but also lower-level cooperation, such as limited travel support. A certain arbitrariness with regard to the time frame cannot be denied, but ICMJE members are not aware of any compelling research evidence on an appropriate time frame. Extending the look-back period to, for example, five or six years runs the risk of creating many unintentionally

false disclosure statements in exchange for very uncertain gain in declaring truly problematic interests and relationships.

For some journals, the inclusion of funding from public institutions or not-for-profit research funders, such as the European Science Foundation, Wellcome Trust, or the Bill and Melinda Gates Foundation, may represent a shift from their current practice. However, even organizations acting pro bono may have an interest-driven research agenda. Also, recent years have seen governments around the globe becoming partisan in their science policy. It is, however, more difficult for readers to see such an agenda of a public research funder than that of a company with obvious stakes in medical market. Therefore, the new form, in the spirit of full disclosure, allows readers to access all possibly relevant relationships and interests. Today, it is hard to tell whether disclosing public or not-for-profit money that goes into the research of an author's working group will create more noise than signal on the disclosure form or will be perceived as helpful in pointing readers to this relatively new source of bias.

As editors of journals, we are ultimately interested not so much in interests and relationships as in bias. It is only because we have learned that interests and relationships often precede bias that we have become more attentive once we know that third-party stakeholders play a role. However, although some authors and their papers may remain unaffected by relationships and interests, the papers of other researchers may be seriously lopsided and unscientific. The judgement about bias cannot be taken away from readers – be they editors, reviewers, or readers of a journal – by looking at a disclosure form.

What disclosure forms can do is to alert readers to possible sources of bias, to enable a look behind the scenes so that we are more vigilant. The new ICMJE disclosure form does just that. It is probably not flawless – no simple form covering a complex issue can ever be – and it is very likely not the last update of the form, but it should serve its main purpose of providing relevant background information to readers.

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