

International Committee of Medical Journal Editors (ICMJE)

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Ethical Considerations in the Conduct and Reporting of Research

II. D. Conflicts of Interest

Public trust in the peer-review process and the credibility of published articles depends in part on how well conflict of interest is handled during writing, peer review, and editorial decision making. Conflict of interest exists when an author (or the author's institution), reviewer, or editor has financial or personal relationships that inappropriately influence (bias) his or her actions (such relationships are also known as dual commitments, competing interests, or competing loyalties). These relationships vary from being negligible to having great potential for influencing judgment. Not all relationships represent true conflict of interest. On the other hand, the potential for conflict of interest can exist regardless of whether an individual believes that the relationship affects his or her scientific judgment. Financial relationships (such as employment, consultancies, stock ownership, honoraria, and paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself. However, conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion.

All participants in the peer-review and publication process must disclose all relationships that could be viewed as potential conflicts of interest. Disclosure of such relationships is also important in connection with editorials

and review articles, because it can be more difficult to detect bias in these types of publications than in reports of original research. Editors may use information disclosed in conflict-of-interest and financial-interest statements as a basis for editorial decisions. Editors should publish this information if they believe it is important in judging the manuscript.

II. D. 1. Potential Conflicts of Interest Related to Individual Authors' Commitments

When authors submit a manuscript, whether an article or a letter, they are responsible for disclosing all financial and personal relationships that might bias their work. To prevent ambiguity, authors must state explicitly whether potential conflicts do or do not exist. Authors should do so in the manuscript on a conflict-of-interest notification page that follows the title page, providing additional detail, if necessary, in a cover letter that accompanies the manuscript. (See Section IV. A. 3. *Conflict-of-Interest Disclosure*.) The ICMJE developed a uniform disclosure form that ICMJE member journals piloted in 2009. The second version of the form is now available, as is an accompanying Glossary. Other journals are welcome to adopt this form.

Authors should identify individuals who provide writing or other assistance and disclose the funding source for this assistance.

Investigators must disclose potential conflicts to study participants and should state in the manuscript whether they have done so.

Editors also need to decide whether to publish information disclosed by authors about potential conflicts. If doubt exists, it is best to err on the side of publication.

II. D. 2. Potential Conflicts of Interest Related to Project Support

Increasingly, individual studies receive funding from commercial firms, private foundations, and government. The conditions of this funding have the potential to bias and otherwise discredit the research.

Scientists have an ethical obligation to submit credible research results for publication. Researchers should not enter into agreements that interfere with their access to all of the data and their ability to analyze them independently, and to prepare and publish manuscripts. Authors should describe the role of the study sponsor, if any, in study design; collection, analysis, and interpretation of data; writing the report; and the decision to submit the report for publication. If the supporting source had no such involvement, the authors should so state. Biases potentially introduced when sponsors are directly involved in research are analogous to methodological biases. Some journals, therefore, choose to include information in the Methods section about the sponsor's involvement.

Editors may request that authors of a study funded by an agency with a proprietary or financial interest in the

Uniform Requirements for Manuscripts Submitted to Biomedical Journals

outcome sign a statement, such as “I had full access to all of the data in this study and I take complete responsibility for the integrity of the data and the accuracy of the data analysis.” Editors should be encouraged to review copies of the protocol and/or contracts associated with project-specific studies before accepting such studies for publication. Editors may request a statistical analysis of all data by an independent biostatistician. Editors may choose not to consider an article if a sponsor has asserted control over the authors’ right to publish.

II. D. 3. Potential Conflicts of Interest Related to Commitments of Editors, Journal Staff, or Reviewers

Editors should avoid selecting external peer reviewers with obvious potential conflicts of interest—for example, those who work in the same department or institution as any of the authors. Authors often provide editors with the names of persons they feel should not be asked to review a manuscript because of potential, usually professional, conflicts of interest. When possible, authors should be asked to explain or justify their concerns; that information is important to editors in deciding whether to honor such requests.

Reviewers must disclose to editors any conflicts of interest that could bias their opinions of the manuscript, and they should recuse themselves from reviewing specific manuscripts if the potential for bias exists. As in the case of authors, silence on the part of reviewers concerning potential conflicts may mean either that conflicts exist and the reviewer has failed to disclose them or conflicts do not exist. Reviewers must therefore also be asked to state explicitly whether conflicts do or do not exist. Reviewers must not use knowledge of the work, before its publication, to further their own interests.

Editors who make final decisions about manuscripts must have no personal, professional, or financial involvement in any of the issues they might judge. Other members of the editorial staff, if they participate in editorial decisions, must provide editors with a current description of their financial interests (as they might relate to editorial judgments) and recuse themselves from any decisions in which a conflict of interest exists. Editorial staff must not use information gained through working with manuscripts for private gain. Editors should publish regular disclosure statements about potential conflicts of interests related to the commitments of journal staff.



ICMJE Form for Disclosure of Potential Conflicts of Interest

Instructions

The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form is designed to be completed electronically and stored electronically. It contains programming that allows appropriate data display. Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information. The form is in four parts.

1. Identifying information.

Enter your full name. If you are NOT the corresponding author please check the box "no" and a space to enter the name of the corresponding author in the space that appears. Provide the requested manuscript information. Double-check the manuscript number and enter it.

2. The work under consideration for publication.

This section asks for information about the work that you have submitted for publication. The time frame for this reporting is that of the work itself, from the initial conception and planning to the present. The requested information is about resources that you received, either directly or indirectly (via your institution), to enable you to complete the work. Checking "No" means that you did the work without receiving any financial support from any third party -- that is, the work was supported by funds from the same institution that pays your salary and that institution did not receive third-party funds with which to pay you. If you or your institution received funds from a third party to support the work, such as a government granting agency, charitable foundation or commercial sponsor, check "Yes". Then complete the appropriate boxes to indicate the type of support and whether the payment went to you, or to your institution, or both.

3. Relevant financial activities outside the submitted work.

This section asks about your financial relationships with entities in the bio-medical arena that could be perceived to influence, or that give the appearance of potentially influencing, what you wrote in the submitted work. You should disclose interactions with ANY entity that could be considered broadly relevant to the work. For example, if your article is about testing an epidermal growth factor receptor (EGFR) antagonist in lung cancer, you should report all associations with entities pursuing diagnostic or therapeutic strategies in cancer in general, not just in the area of EGFR or lung cancer.

Report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the 36 months prior to submission of the work. This should include all monies from sources with relevance to the submitted work, not just monies from the entity that sponsored the research. Please note that your interactions with the work's sponsor that are outside the submitted work should also be listed here. If there is any question, it is usually better to disclose a relationship than not to do so.

For grants you have received for work outside the submitted work, you should disclose support ONLY from entities that could be perceived to be affected financially by the published work, such as drug companies, or foundations supported by entities that could be perceived to have a financial stake in the outcome. Public funding sources, such as government agencies, charitable foundations or academic institutions, need not be disclosed. For example, if a government agency sponsored a study in which you have been involved and drugs were provided by a pharmaceutical company, you need only list the pharmaceutical company.

4. Other relationships.

Use this section to report other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work.



ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) _____ 2. Surname (Last Name) _____ 3. Effective Date (07-August-2008) _____
4. Are you the corresponding author? Yes No
5. Manuscript Title _____
6. Manuscript Identifying Number (if you know it) _____

Section 2. The Work Under Consideration for Publication

Did you or your institution at any time receive payment or services from a third party for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc...)?

Complete each row by checking "No" or providing the requested information. If you have more than one relationship click the "Add" button to add a row. Excess rows can be removed by clicking the "X" button.

The Work Under Consideration for Publication

Type	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**	
1. Grant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD
2. Consulting fee or honorarium	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD
3. Support for travel to meetings for the study or other purposes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD
4. Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD
5. Payment for writing or reviewing the manuscript	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD
6. Provision of writing assistance, medicines, equipment, or administrative support	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X



ICMJE Form for Disclosure of Potential Conflicts of Interest

The Work Under Consideration for Publication

Type	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**	
						ADD
7. Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD

* This means money that your institution received for your efforts on this study.

** Use this section to provide any needed explanation.

Section 3. Relevant financial activities outside the submitted work.

Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were present during the 36 months prior to submission.

Complete each row by checking "No" or providing the requested information. If you have more than one relationship click the "Add" button to add a row. Excess rows can be removed by clicking the "X" button.

Relevant financial activities outside the submitted work

Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your Institution*	Entity	Comments	
1. Board membership	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD
2. Consultancy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD
3. Employment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD
4. Expert testimony	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD
5. Grants/grants pending	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD
6. Payment for lectures including service on speakers bureaus	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X
						ADD
7. Payment for manuscript preparation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			X



ICMJE Form for Disclosure of Potential Conflicts of Interest

Relevant financial activities outside the submitted work						
Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your Institution*	Entity	Comments	
8. Patents (planned, pending or issued)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			ADD X
9. Royalties	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			ADD X
10. Payment for development of educational presentations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			ADD X
11. Stock/stock options	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			ADD X
12. Travel/accommodations/ meeting expenses unrelated to activities listed**	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			ADD X
13. Other (err on the side of full disclosure)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			ADD X

* This means money that your institution received for your efforts.

** For example, if you report a consultancy above there is no need to report travel related to that consultancy on this line.

Section 4. Other relationships

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

- No other relationships/conditions/circumstances that present a potential conflict of interest
- Yes, the following relationships/conditions/circumstances are present (explain below):

At the time of manuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. On occasion, journals may ask authors to disclose further information about reported relationships.

Hide All Table Rows Checked 'No'

SAVE



ICMJE Form for Disclosure of Potential Conflicts of Interest

Evaluation and Feedback

Please visit <http://www.icmje.org/cgi-bin/feedback> to provide feedback on your experience with completing this form.