

## **ICMJE Uniform Disclosure Form for 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 has five parts.

#### **1. Identifying information.**

Each author should submit a separate form. Provide complete information and double-check the manuscript number. If you are NOT the corresponding author please insert his or her name.

#### **2. The work under consideration for publication.**

Please provide 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 idea is to provide for the reader information about resources that you received, either directly or indirectly (via your institution), to enable you to complete the work. If you check the "No" box it 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 to pay you. If you or your institution did receive funds from a third party to support the work, check "Yes" along with the appropriate boxes to indicate the type of support and whether you or your institution received it.

#### **3. Relevant financial activities outside the submitted work.**

Please report all sources of revenue relevant to the submitted work that accrued either directly to you or were paid to 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. If there is any question, it is usually better to disclose a relationship than not to do so. Please note that your interactions with the work's sponsor outside the submitted work should be listed here. For each category list each entity on a separate line. Use as many lines as necessary to provide complete information. In addition, please disclose relationships that fall outside the 36-month window that readers may want to know about and could reasonably criticize you for not disclosing (for example, long-term financial relationships that are now ended).

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#### **4. Financial relationships involving your spouse or partner or your children (under 18 years of age).**

If monies from the types of relationships listed in Section 3 were paid to your spouse or partner or dependent children, please list the type of activity and source of the money.

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Please report any personal, professional, political, institutional, religious, or other associations that a reasonable reader would want to know about in relation to the submitted work.



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### Section 1. Identifying Information.

Given Name:  Surname:  Effective Date:

(or first)

(or last)

Effective Date:

14-December-2009

Format example: 07-August-2008

Are you the corresponding author?  Yes  No

Corresponding author's name:

Manuscript Title:

Manuscript Identifying Number (if you know it):

### Section 2. Information about the support of the work under consideration for publication.

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

No

Yes, specify nature of compensation

If you have more than one relationship, click "Add +" to add a row. Click "Del x" to delete an extra row.

Type	Money Paid to You*		Money to Your Institution		Name of Entity	Comments**	
	No	Yes	No	Yes			
Grant	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Risk MR, LLC	The study was supported by Sepracor. My institution, Risk MR Pharmacovigilance Services, SL collaborated with Risk MR, LLC	Del x
							Add +
Consulting fee or honorarium	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del x
							Add +
Support for travel to meetings for the study or otherwise	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Sepracor		Del x
							Add +
Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Risk MR, LLC		Del x
							Add +



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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Payment for writing or reviewing the manuscript	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Risk MR, LLC		Del ×
							Add +
Support in kind such as writing, provision of medicines or equipment, or administrative support	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Risk MR, LLC		Del ×
							Add +
Other	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del ×
							Add +

\*\*Use this section to provide any needed explanation

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If you have more than one relationship, click "Add +" to add a row. Click "Del ×" to delete an extra row.

Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your institution	Entity	Comments	
Board membership	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Consultancy	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	UCB Pharma	Not related to Antiepileptics	Del ×
Consultancy	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Novartis	Not related to Antiepileptics	Del ×
						Add +
Employment	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Pfizer	Employee from 2002 to 2005	Del ×
Employment	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Novartis	Employee from 1996 to 2002	Del ×
						Add +
Expert testimony	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×



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Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your institution	Entity	Comments	
						Add +
Gifts	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Grants/grants pending	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Novartis	Not related to the project	Del ×
						Add +
Honoraria	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Payment for manuscript preparation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Patents (planned, pending or issued)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Royalties	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Payment for development of educational presentations including service on speakers' bureaus	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Stock/stock options	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Travel/accommodations expenses covered or reimbursed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Other (err on the side of full disclosure)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +

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Do your children or your spouse or partner have financial relationships with entities that have an interest in the content of the submitted work?

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

### **Section 5. Information about relevant nonfinancial associations.**

Do you have any relevant nonfinancial associations or interests (personal, professional, political, institutional, religious, or other) that a reasonable reader would want to know about in relation to the submitted work?

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 (or first) (or last) Format example: 07-August-2008

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- No  
 Yes, specify nature of compensation

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Type	Money Paid to You*		Money to Your Institution		Name of Entity	Comments**	
	No	Yes	No	Yes			
Grant	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Risk Mr, LLC	The study was supported by Sepracor	Del x
							Add +
Consulting fee or honorarium	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del x
							Add +
Support for travel to meetings for the study or otherwise	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del x
							Add +
Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del x
							Add +
Payment for writing or reviewing the manuscript	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del x
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
Support in kind such as writing, provision of medicines or equipment, or administrative support	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del ×
							Add +
Other	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del ×
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Board membership	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Consultancy	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	UCB, Novartis, JNJ	Unrelated to this project	Del ×
						Add +
Employment	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Novartis, Pfizer	Novartis until 1997, Pfizer briefly until 2004	Del ×
						Add +
Expert testimony	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Gifts	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Grants/grants pending	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Novartis	Ongoing grant on unrelated project	Del ×



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Honoraria	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Payment for manuscript preparation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Patents (planned, pending or issued)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Royalties	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Payment for development of educational presentations including service on speakers' bureaus	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Stock/stock options	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Travel/accommodations expenses covered or reimbursed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Other (err on the side of full disclosure)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +

**Section 4. Information about financial relationships involving your spouse or partner or your children (under 18 years of age).**

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Format example: 07-August-2008

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Type	Money Paid to You*		Money to Your Institution		Name of Entity	Comments**	
	No	Yes	No	Yes			
Grant	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del x
							Add +
Consulting fee or honorarium	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Risk Mr, LLC	Payment for services rendered on the study presented in this paper	Del x
							Add +
Support for travel to meetings for the study or otherwise	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del x
							Add +
Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del x
							Add +
Payment for writing or reviewing the manuscript	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del x



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							Add +
Support in kind such as writing, provision of medicines or equipment, or administrative support	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del ×
							Add +
Other	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del ×
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Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your institution	Entity	Comments	
Board membership	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Consultancy	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Lundbeck S.A.	Preparation of the research protocol for a study on the diagnostic delay in first episode of depression in contact with health care centers in Spain. Unrelated to this project	Del ×
						Add +
Employment	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +



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Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your institution	Entity	Comments	
Expert testimony	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Sanofi Aventis S.A.	Expert testimony on the side effects of verapride. Unrelated to this project	Del ×
						Add +
Gifts	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Grants/grants pending	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Honoraria	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
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						Add +
Patents (planned, pending or issued)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Royalties	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Payment for development of educational presentations including service on speakers' bureaus	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Stock/stock options	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Travel/accommodations expenses covered or reimbursed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
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Each author should submit a separate form. Provide complete information and double-check the manuscript number. If you are NOT the corresponding author please insert his or her name.

#### 2. The work under consideration for publication.

Please provide 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 idea is to provide for the reader information about resources that you received, either directly or indirectly (via your institution), to enable you to complete the work. If you check the "No" box it 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 to pay you. If you or your institution did receive funds from a third party to support the work, check "Yes" along with the appropriate boxes to indicate the type of support and whether you or your institution received it.

#### 3. Relevant financial activities outside the submitted work.

Please report all sources of revenue relevant to the submitted work that accrued either directly to you or were paid to 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. If there is any question, it is usually better to disclose a relationship than not to do so. Please note that your interactions with the work's sponsor outside the submitted work should be listed here. For each category list each entity on a separate line. Use as many lines as necessary to provide complete information. In addition, please disclose relationships that fall outside the 36-month window that readers may want to know about and could reasonably criticize you for not disclosing (for example, long-term financial relationships that are now ended).

The goal of this section is to provide information for our reviewers and readers about your interactions with entities in the biomedical 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. For grants you have received for work outside the submitted work, you should disclose support ONLY from entities that could be perceived to benefit financially from 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 the NIH or the MRC, need not be disclosed. For example, if the NIH sponsored a piece of work you have been involved in but drugs were provided by a pharmaceutical company, you need only list the pharmaceutical company.

#### 4. Financial relationships involving your spouse or partner or your children (under 18 years of age).

If monies from the types of relationships listed in Section 3 were paid to your spouse or partner or dependent children, please list the type of activity and source of the money.

#### 5. Nonfinancial associations.

Please report any personal, professional, political, institutional, religious, or other associations that a reasonable reader would want to know about in relation to the submitted work.



## ICMJE Uniform Disclosure Form for Potential Conflicts of Interest

### Section 1. Identifying Information.

Given Name:  Surname:  Effective Date:

(or first)

(or last)

Format example: 07-August-2008

Are you the corresponding author?  Yes  No

Corresponding author's name:

Manuscript Title:

Manuscript Identifying Number (if you know it):

### Section 2. Information about the support of the work under consideration for publication.

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

No

Yes, specify nature of compensation

If you have more than one relationship, click "Add +" to add a row. Click "Del x" to delete an extra row.

Type	Money Paid to You*		Money to Your Institution		Name of Entity	Comments**	
	No	Yes	No	Yes			
Grant	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del x
							Add +
Consulting fee or honorarium	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Risk Management Resources		Del x
							Add +
Support for travel to meetings for the study or otherwise	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del x
							Add +
Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del x
							Add +
Payment for writing or reviewing the manuscript	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del x



**ICMJE Uniform Disclosure Form for Potential Conflicts of Interest**

Type	Money Paid to You*		Money to Your Institution		Name of Entity	Comments**	
							Add +
Support in kind such as writing, provision of medicines or equipment, or administrative support	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del ×
							Add +
Other	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			Del ×
							Add +

\*\*Use this section to provide any needed explanation

**Section 3. Information about relevant financial relationships 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 any entities that have an interest related to the submitted work. Use one line for each entity; add as many lines as you need. Use the comments column to indicate any additional information that you think a reader or editor would want to know about the compensation. Report relationships that were present during the 36 months prior to submission. In addition please disclose relationships that fall outside the 36-month window that readers may want to know about and could reasonably criticize you for not disclosing (for example, long-term financial relationships that are now ended).

If you have more than one relationship, click "Add +" to add a row. Click "Del ×" to delete an extra row.

Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your institution	Entity	Comments	
Board membership	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Consultancy	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Risk Management Resources		Del ×
						Add +
Employment	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Expert testimony	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Gifts	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Grants/grants pending	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×



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Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your institution	Entity	Comments	
						Add +
Honoraria	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Payment for manuscript preparation	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Risk Management Resources		Del ×
						Add +
Patents (planned, pending or issued)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Royalties	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Payment for development of educational presentations including service on speakers' bureaus	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Stock/stock options	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Travel/accommodations expenses covered or reimbursed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +
Other (err on the side of full disclosure)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			Del ×
						Add +

**Section 4. Information about financial relationships involving your spouse or partner or your children (under 18 years of age).**

Do your children or your spouse or partner have financial relationships with entities that have an interest in the content of the submitted work?

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

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### **Section 5. Information about relevant nonfinancial associations.**

Do you have any relevant nonfinancial associations or interests (personal, professional, political, institutional, religious, or other) that a reasonable reader would want to know about in relation to the submitted work?

- No relevant nonfinancial relationships/conditions/circumstances to report.
- Yes, the following relevant nonfinancial 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.

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