

Instructions

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Identifying information.

2. The work under consideration for publication.

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3. Relevant financial activities outside the submitted work.

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4. Intellectual Property.

This section asks about patents and copyrights, whether pending, issued, licensed and/or receiving royalties.

Relationships not covered above.

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Other: Anything not covered under the previous three boxes

Pending: The patent has been filed but not issued

Issued: The patent has been issued by the agency

Licensed: The patent has been licensed to an entity, whether earning royalties or not

Royalties: Funds are coming in to you or your institution due to your patent

Lehman 1



Section 1. Identifying Infor	mation						
1. Given Name (First Name) Richard	2. Surname (Last Name) Lehman	3. Date 28-May-2013					
4. Are you the corresponding author?	Yes Vo	Corresponding Author's Name Harlan M Krumholz					
5. Manuscript Title An historic moment for open science: the Yale Open Data Access Project and Medtronic							
6. Manuscript Identifying Number (if you l M13-1142	know it)						
		_					
Section 2. The Work Under 0	Consideration for Public	cation					
	ng but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ta monitoring board, study design, manuscript preparation,					
Section 3. Relevant financia	l activities outside the s	submitted work.					
of compensation) with entities as desc	ribed in the instructions. Us eport relationships that wer	ether you have financial relationships (regardless of amount se one line for each entity; add as many lines as you need by re present during the 36 months prior to publication.					
Section 4. Intellectual Property							
Intellectual Prope	erty Patents & Copyric	hts					
Do you have any patents, whether pla	nned, pending or issued, br	oadly relevant to the work? Yes V No					

Lehman 2



Section 5.								
	Relationships not covered above							
	elationships or activities that readers could perceive to have influenced, or that give the appearance of encing, what you wrote in the submitted work?							
Yes, the follow	Yes, the following relationships/conditions/circumstances are present (explain below):							
✓ No other rela	tionships/conditions/circumstances that present a potential conflict of interest							
	anuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements rnals may ask authors to disclose further information about reported relationships.							
Section 6.	Disclosure Statement							
Based on the abo	ove disclosures, this form will automatically generate a disclosure statement, which will appear in the box							
No disclosures								

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Emanuel 1



Section 1.	Identifying Inform	Identifying Information							
1. Given Name (Fii Ezekiel	rst Name)	2. Surname (Last Name) Emanuel	3. Date 28-May-2013						
4. Are you the cor	responding author?	✓ Yes No	✓ Yes No						
5. Manuscript Title An historic moment for open science: The Yale Open Data Access Project and Medtronic									
6. Manuscript lder M13-1142	ntifying Number (if you kr	now it)							
Section 2.	The Work Under C	onsideration for Publica	tion						
any aspect of the s statistical analysis,	ubmitted work (including	but not limited to grants, data	–	ommercial, private foundation, etc.) for esign, manuscript preparation,					
Section 3.	Relevant financial	activities outside the sul	omitted work.						
of compensation clicking the "Add Are there any rel) with entities as descri	ibed in the instructions. Use oport relationships that were p	one line for each entity; a	lationships (regardless of amount add as many lines as you need by nonths prior to publication .					
Section 4.	Intellectual Prope	rty Patents & Copyrigh	ts						
Do you have any	patents, whether plan	ned, pending or issued, broa	dly relevant to the work?	? ☐ Yes ✓ No					

Emanuel 2



Section 5.	lationships not covered above
	onships or activities that readers could perceive to have influenced, or that give the appearance of g, what you wrote in the submitted work?
✓ Yes, the following	relationships/conditions/circumstances are present (explain below):
No other relations	ships/conditions/circumstances that present a potential conflict of interest
YODA pays for his ser	vices as chair on their Advisory Board (\$15,000) annually.
	cript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements may ask authors to disclose further information about reported relationships.
Section 6. Dis	closure Statement
Based on the above of below.	lisclosures, this form will automatically generate a disclosure statement, which will appear in the box
Dr. Emanuel reports	and YODA pays for his services as chair on their Advisory Board (\$15,000) annually

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Emanuel 3



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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.

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Section 1.	Identifying Infor	mation		
1. Given Name (Fi Joseph	irst Name)	2. Surname (Last Name) Ross		3. Effective Date (07-August-2008) 14-May-2013
4. Are you the cor	responding author?	Yes Vo	Corresponding Author's Na Harlan M. Krumholz, MD,	
5. Manuscript Title An historic mom		the Yale Open Data Acces	s Project and Medtronic	
6. Manuscript lde M13-1142	ntifying 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						
Туре	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**	
1. Grant			√	Medtronic, Inc.	Dr. Ross is currently supported by Medtronic, Inc. to develop the Yale University Open Access Data project.	×
						ADD
2. Consulting fee or honorarium	✓					×
						ADD
3. Support for travel to meetings for the study or other purposes	✓					×
						ADD
4. Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like	✓					×
						ADD
Payment for writing or reviewing the manuscript	✓					×



The Work Under Consideration for Publication						
Туре	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**	
						ADD
Provision of writing assistance, medicines, equipment, or administrative support	√					×
						ADD
7. Other	✓					×
						ADD

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.

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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		✓		FAIR Health, Inc. Scientific Advisory Board	FAIR Health, Inc. is a non- profit organization established in October 2009 with the mission to help ensure fairness and transparency in out-of- network reimbursement	×
						ADD
2. Consultancy	✓					×
						ADD
3. Employment	✓					X
						ADD
4. Expert testimony	✓					×

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

^{**} Use this section to provide any needed explanation.



Relevant financial activities out	side the	submit	ted work			
Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your Institution*	Entity	Comments	
						ADD
5. Grants/grants pending			✓	National Institute on Aging/American Federation of Aging Research	Dr. Ross is currently supported by the National Institute on Aging (K08 AG032886) and by the American Federation of Aging Research through the Paul B. Beeson Career Development Award Program.	×
5. Grants/grants pending			✓	Food and Drug Administration (FDA)	Dr. Ross receives support from the FDA for a research grant to determine best practices in medical device post- market surveillance	×
5. Grants/grants pending			✓	Pew Charitable Trusts	Dr. Ross is currently supported by the Pew Charitable Trusts to examine FDA regulatory review issues.	×
						ADD
Payment for lectures including service on speakers bureaus	✓					×
						ADD
Payment for manuscript preparation	✓					×
						ADD
Patents (planned, pending or issued)	√					×
						ADD
9. Royalties	√					×
						ADD
Payment for development of educational presentations	✓					×
						ADD
11. Stock/stock options	✓					X
						ADD



12. Travel/accommodations/ meeting expenses unrelated to activities listed**	√					×
						ADD
13. Other (err on the side of full disclosure)			✓	Centers for Medicare and Medicaid Services (CMS)	Dr. Ross receives support via contract with the CMS to develop and maintain performance measures that are used for public reporting.	×
* 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 relationsh	nips					
Are there other relationships or active potentially influencing, what you wro			•	to have influenced, or th	nat give the appearance of	
✓ 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						

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Krumholz 1



Section 1.	Identifying Informa	ation						
1. Given Name (Firs Harlan	t Name)	2. Surnar Krumhol	ne (Last Nar z	me)		3. Date 20-May-2013		
4. Are you the corre	sponding author?	✓ Yes No						
5. Manuscript Title An historic mome	nt for open science: the	e Yale Op	en Data Ad	cess Project and	Medtroni	c"		
6. Manuscript Ident M13-1142	ifying Number (if you kno	ow it)						
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any aspect of the sul statistical analysis, e	bmitted work (including l	out not lim	ited to grar		-	ent, commercial, private foundation, etc.) for udy design, manuscript preparation,		
	it the appropriate infoi e removed by pressing			u have more thar	one enti	ty press the "ADD" button to add a row.		
Name of Institution	on/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments		
Medtronic, Inc.		✓				Research grant/Independent assessment of INFUSE data		
Food and Drug Admini	istration	✓				Optimizing Medical Device Post- Market Surveillance for Public Value		
Section 3.	Relevant financial a	ctivities	outside	the submitted	work.			
of compensation) clicking the "Add -	with entities as describ +" box. You should rep	ed in the ort relatio	instruction nships tha	ns. Use one line fo t were present d	or each er	rial relationships (regardless of amount nity; add as many lines as you need by 2 36 months prior to publication.		
•	vant conflicts of interes			No				
ii yes, piease iiii ot	ıt the appropriate infoi	mation D	eiow.					
Name of Entity		Grant?	Personal Fees	Non-Financial Support?	Other?	Comments		
JnitedHealthcare, Inc.			√			Chair, Cardiac Scientific Advisory		

Krumholz 2



Section 4.	Intellectual Property Patents & Copyrights
Do you have any	patents, whether planned, pending or issued, broadly relevant to the work? Yes V
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Section 1.	Identifying Infor	mation		
1. Given Name (Fi Beth	rst Name)	2. Surname (Last Name) Hodshon		3. Effective Date (07-August-2008) 14-May-2013
4. Are you the corresponding author?		Yes ✓ No	Corresponding Author's Na Harlan M. Krumholz, MD,	
5. Manuscript Title An historic mom		the Yale Open Data Access	Project and Medtronic	
6. Manuscript Ide M13-1142	ntifying Number (if you l	know it)		

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1. Grant			V	Medtronic, Inc.	Ms. Hodshon is currently supported by Medtronic, Inc. to develop the Yale University Open Access Data project.	×
						ADD
2. Consulting fee or honorarium	✓					×
						ADD
3. Support for travel to meetings for the study or other purposes	✓					×
						ADD
 Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like 	✓					×
						ADD
Payment for writing or reviewing the manuscript	✓					×



The Work Under Consideration for Publication						
Туре	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**	
						ADD
Provision of writing assistance, medicines, equipment, or administrative support	√					×
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7. Other	✓					×
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						ADD
2. Consultancy	\checkmark					×
						ADD
3. Employment	\checkmark					×
						ADD
4. Expert testimony	\checkmark					×
						ADD
5. Grants/grants pending	\checkmark					×

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

^{**} Use this section to provide any needed explanation.



Relevant financial activities out	side the	submit	ted work			
Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your Institution*	Entity	Comments	
5. Grants/grants pending			√	Food and Drug Administration (FDA)	Ms. Hodshon receives support from the FDA for a research grant to determine best practices in medical device post- market surveillance	×
5. Grants/grants pending	✓					×
						ADD
Payment for lectures including service on speakers bureaus	✓					×
7. Danisa de la companie de la compan						ADD
Payment for manuscript preparation	✓					×
						ADD
Patents (planned, pending or issued)	✓					×
						ADD
9. Royalties	✓					×
						ADD
Payment for development of educational presentations	√					×
						ADD
11. Stock/stock options	✓					X
12. Travel/accommodations/						ADD
meeting expenses unrelated to activities listed**	✓					×
						ADD
Other (err on the side of full disclosure)	✓					×
						ADD

^{*} 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.



Continu /	
Section 4.	Other relationships
	elationships or activities that readers could perceive to have influenced, or that give the appearance of ncing, what you wrote in the submitted work?
✓ No other rela	tionships/conditions/circumstances that present a potential conflict of interest
Yes, the follow	wing relationships/conditions/circumstances are present (explain below):
	nuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. rnals may ask authors to disclose further information about reported relationships.
	Hide All Table Rows Checked 'No' SAVE

Evaluation and Feedback

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



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.



Section 1.	Identifying Infor	mation		
1. Given Name (Fi Jessica	rst Name)	2. Surname (Last Name) Ritchie		3. Effective Date (07-August-2008) 14-May-2013
4. Are you the corresponding author?		☐ Yes ✓ No	Corresponding Author's Na Harlan M. Krumholz, MD,	
5. Manuscript Title An historic mom		the Yale Open Data Acces	s Project and Medtronic	
6. Manuscript Ide M13-1142	ntifying 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 f	or Publ	lication				
Туре	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**	
1. Grant			✓	Medtronic, Inc.	Ms. Ritchie is currently supported by Medtronic, Inc. to develop the Yale University Open Access Data Project.	×
						ADD
2. Consulting fee or honorarium	✓					×
						ADD
3. Support for travel to meetings for the study or other purposes	✓					×
						ADD
 Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like 	✓					×
						ADD
Payment for writing or reviewing the manuscript	✓					×



The Work Under Consideration for Publication						
Туре	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**	
						ADD
Provision of writing assistance, medicines, equipment, or administrative support	√					×
						ADD
7. Other	✓					×
						ADD

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	✓					×
						ADD
2. Consultancy	\checkmark					×
						ADD
3. Employment	\checkmark					×
						ADD
4. Expert testimony	\checkmark					×
						ADD
5. Grants/grants pending	\checkmark					×

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^{**} Use this section to provide any needed explanation.



Relevant financial activities out	side the	submit	ted work			
Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your Institution*	Entity	Comments	
5. Grants/grants pending			√	Food and Drug Administration (FDA)	Ms. Ritchie receives support from the FDA for a research grant to determine best practices in medical device post- market surveillance	×
5. Grants/grants pending	✓					×
						ADD
Payment for lectures including service on speakers bureaus	✓					×
						ADD
Payment for manuscript preparation	✓					×
						ADD
Patents (planned, pending or issued)	✓					×
						ADD
9. Royalties	✓					×
						ADD
Payment for development of educational presentations	✓					×
						ADD
11. Stock/stock options	✓					×
						ADD
12. Travel/accommodations/ meeting expenses unrelated to activities listed**	✓					×
						ADD
13. Other (err on the side of full disclosure)	✓					×
						ADD

^{*} 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
	elationships or activities that readers could perceive to have influenced, or that give the appearance of ncing, what you wrote in the submitted work?
	tionships/conditions/circumstances that present a potential conflict of interest wing relationships/conditions/circumstances are present (explain below):
	nuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. raals may ask authors to disclose further information about reported relationships.
	Hide All Table Rows Checked 'No'

Evaluation and Feedback

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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.

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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.



Section 1. Identifying Infor	mation	
Given Name (First Name) Cary	2. Surname (Last Name) Gross	3. Effective Date (07-August-2008) 20-November-2012
4. Are you the corresponding author?	☐ Yes 🗸 No	Corresponding Author's Name Harlan Krumholz, MD
5. Manuscript Title Clinical Trial data sharing		
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							
Туре	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**		
1. Grant			✓	Medtronic Inc	I am receiving funding as a collaborator on the "Yale University Open Data Access" Project, which is facilitating objective analysis of Medtronic clinical trial data.	×	
						ADD	
2. Consulting fee or honorarium	✓					×	
						ADD	
Support for travel to meetings for the study or other purposes	✓					×	
						ADD	
 Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like 	✓					×	
						ADD	



The Work Under Consideration for Publication						
Туре	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**	
5. Payment for writing or reviewing the manuscript	✓					×
						ADD
Provision of writing assistance, medicines, equipment, or administrative support	√					×
						ADD
7. Other	\checkmark					×
						ADD

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.

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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		✓		Fair Health Inc	Scientific Advisory Board Member	×	
						ADD	
2. Consultancy	✓					×	
						ADD	
3. Employment	✓					×	
						ADD	
4. Expert testimony	✓					×	
						ADD	
5. Grants/grants pending	✓					×	

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

^{**} Use this section to provide any needed explanation.



Relevant financial activities outside the submitted work						
Type of Relationship (in alphabetical order)	No	Money Paid to You	Money to Your Institution*	Entity	Comments	
						ADD
Payment for lectures including service on speakers bureaus	✓					×
						ADD
Payment for manuscript preparation	✓					×
						ADD
Patents (planned, pending or issued)	✓					×
						ADD
9. Royalties	✓					×
						ADD
Payment for development of educational presentations	✓					×
						ADD
11. Stock/stock options	✓					×
						ADD
12. Travel/accommodations/ meeting expenses unrelated to activities listed**	√					×
						ADD
Other (err on the side of full disclosure)	✓					×
						ADD

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):

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Hide All Table Rows Checked 'No'

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