

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) Furqan	2. Surname (Last Name) Butt	3. Effective Date 12/10/23
4. Are you the corresponding author? ☐ Yes ☒ No		
Corresponding Author's Name Mohamed Fawzy		
5. Manuscript Title: The Randomized Clinical Trial Trustworthiness Crisis		
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	☒	☐	☐			X
						ADD
2. Consulting fee or honorarium	☒	☐	☐			X
						ADD
3. Support for travel to meetings for the study or other purposes	☒	☐	☐			X
						ADD
4. Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like	☒	☐	☐			X
						ADD
5. Payment for writing or reviewing the manuscript	☒	☐	☐			X
						ADD
6. Provision of writing assistance, medicines, equipment, or administrative support	☒	☐	☐			X

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The Work Under Consideration for Publication						
Type	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**	
						ADD
7. Other	☒	☐	☐			×
7. Other	☒	☐	☐			×
7. Other	☒	☐	☐			×

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7. Other	☒	☐	☐			×
7. Other	☒	☐	☐			×
						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

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	
1. Board membership	☒	☐	☐			×
2. Consultancy	☒	☐	☐			ADD ×
3. Employment	☒	☐	☐			ADD ×
4. Expert testimony	☒	☐	☐			×
						ADD

ICMJE Form for Disclosure of Potential Conflicts of Interest

5. Grants/grants pending	☒	☐	☐			×
						ADD
6. Payment for lectures including service on speakers bureaus	☒	☐	☐			×
						ADD
7. Payment for manuscript preparation	☒	☐	☐			×
						ADD
8. Patents (planned, pending or issued)	☒	☐	☐			×
						ADD
9. Royalties	☒	☐	☐			×
						ADD
10. Payment for development of educational presentations	☒	☐	☐			×
						ADD
11. Stock/stock options	☒	☐	☐			×
						ADD
12. Travel/accommodations/meeting expenses unrelated to activities listed**	☒	☐	☐			×
						ADD

ICMJE Form for Disclosure of Potential Conflicts of Interest

13. Other (err on the side of full disclosure)	☒	☐	☐			✕
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

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

Evaluation and Feedback

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

ICMJE Form for Disclosure of Potential Conflicts of Interest

ICMJE DISCLOSURE FORM

Date: 12/10/2023

Your Name: Mohamed Fawzy

Manuscript Title: The Randomized Clinical Trial Trustworthiness Crisis

Manuscript Number (if known): Not applicable

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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	Click the tab key to add additional rows.							
Time frame: past 36 months								
2	Grants or contracts from any entity (if not indicated in item #1 above).	☒ None <table border="1"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>						

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		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)								
3	Royalties or licenses	☒ None <table border="1" data-bbox="370 447 1507 546"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>									
4	Consulting fees	☒ None <table border="1" data-bbox="370 688 1507 821"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>									
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	☒ None <table border="1" data-bbox="370 909 1507 1005"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>									
6	Payment for expert testimony	☒ None <table border="1" data-bbox="370 1239 1507 1337"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>									
7	Support for attending meetings and/or travel	☒ None <table border="1" data-bbox="370 1455 1507 1554"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>									
8	Patents planned, issued or pending	☒ None <table border="1" data-bbox="370 1673 1507 1772"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>									
9	Participation on a Data Safety Monitoring Board or Advisory Board	☒ None <table border="1" data-bbox="370 1890 1507 1988"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>									

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		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	☐ None	
		Middle East Fertility Society Journal (MEFS)	Deputy Editor without honoraria
			I am not aware of any paper handled subjected to retraction or expression of concern.
		Upper Egypt Assisted Reproduction Conference (UEARS)	I am a cofounder of this education activity organized in Egypt every year since 2016.
11	Stock or stock options	☒ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	☒ None	
13	Other financial or non-financial interests	☐ None	
		Randomised controlled trials	I have co-authored RCTs which was non-funded. None of my trials have been subjected to a retraction or expression of concern. I fully comply with COPE guidelines for pre- and post-publication issues.
		Systematic reviews	I have co-authored a systematic review which were non-funded. To the best of my knowledge, this systematic review has not been subjected to a retraction or expression of concern.
		Artificial intelligence	I have co-authored paper to train AI model to predict best embryo which was non-funded.

Please place an "X" next to the following statement to indicate your agreement:

☒ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE Form for Disclosure of Potential Conflicts of Interest

ICMJE DISCLOSURE FORM

Date: 12/10/2023

Your Name: Yacoub Khalaf

Manuscript Title: The Randomized Clinical Trial Trustworthiness Crisis

Manuscript Number (if known): Not applicable

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

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Time frame: Since the initial planning of the work								
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	☒ None <table border="1"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td>Click the tab key to add additional rows.</td></tr> </table>						Click the tab key to add additional rows.
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Time frame: past 36 months								
2	Grants or contracts from any entity (if not indicated in item #1 above).	☒ None <table border="1"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>						

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3	Royalties or licenses	☒ None <table border="1" data-bbox="371 449 1507 546"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>									
4	Consulting fees	☒ None <table border="1" data-bbox="371 693 1507 821"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>									
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	☒ None <table border="1" data-bbox="371 911 1507 1037"> <tr> <td>Merck, IBSA, Ferring Pharmaceuticals, LD Collins</td> <td>Honoraria for lectures</td> </tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>	Merck, IBSA, Ferring Pharmaceuticals, LD Collins	Honoraria for lectures							
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8	Patents planned, issued or pending	☒ None <table border="1" data-bbox="371 1673 1507 1770"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>									
9	Participation on a Data Safety Monitoring Board or Advisory Board	☒ None <table border="1" data-bbox="371 1890 1507 1986"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table>									

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10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	☒ None	
11	Stock or stock options	☒ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	☒ None	
13	Other financial or non-financial interests	☐ None	
		Randomised controlled trials	I have co-authored a RCTs. To the best of my knowledge, this trial has not been subjected to a retraction or expression of concern.
		Systematic reviews	I have co-authored several systematic reviews. To the best of my knowledge, none of these systematic reviews has been subjected to a retraction or expression of concern.

Please place an "X" next to the following statement to indicate your agreement:

☒ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

Please wait...

If this message is not eventually replaced by the proper contents of the document, your PDF viewer may not be able to display this type of document.

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For more assistance with Adobe Reader visit <http://www.adobe.com/go/acrreader>.

Windows is either a registered trademark or a trademark of Microsoft Corporation in the United States and/or other countries. Mac is a trademark of Apple Inc., registered in the United States and other countries. Linux is the registered trademark of Linus Torvalds in the U.S. and other countries.

ICMJE DISCLOSURE FORM

Date: 9/10/2022

Your Name: Aurora Bueno-Cavanillas

Manuscript Title: The Randomized Clinical Trial Trustworthiness Crisis

Manuscript Number (if known): [Click or tap here to enter text.]

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

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Section 1.

Identifying Information

1. Given Name (First Name)

Khalid Saeed

2. Surname (Last Name)

Khan

3. Effective Date

26-July-2023

4. Are you the corresponding author?

☐

Yes

☒

No

Corresponding Author's Name

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...)?

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Type	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**	
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						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
5. Payment for writing or reviewing the manuscript	☒	☐	☐			×
						ADD
6. Provision of writing assistance, medicines, equipment, or administrative support	☒	☐	☐			×

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The Work Under Consideration for Publication						
Type	No	Money Paid to You	Money to Your Institution*	Name of Entity	Comments**	
7. Other	☐	☒	☐	Journal editorship	I am editor of Research Topic: Integrity of Randomised Controlled trials (2022-2023) in Frontiers in Public Health. I was former editor of BJOG (2009-2018, chief editor 2012-2018), BMJ-EBM (2008-2019), BMC Med Ed (2008-2012). I received an honorarium payment for my BJOG editorship. To my knowledge, of these journals, only BJOG publishes randomised clinical trials (RCTs) and it has had some RCTs retracted outside my chief editorship of the journal.	ADD
7. Other	☒	☐	☐	Randomised clinical trials (RCTs)	I have co-authored various RCTs including some that have been grant funded. None of these have been subjected to retractions or expressions of concern.	x
7. Other	☒	☐	☐	Systematic reviews	I have co-authored various systematic reviews of RCTs including some that have been grant funded. To the best of my knowledge, none of these have included RCTs that been subjected to retractions or expressions of concern. I have not been made aware of any included RCT retraction subsequent to publication of the systematic reviews.	x

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7. Other	☒	☐	☐	Trial oversight	I have been member of trial steering committees and data monitoring committees in various randomised and non-randomised clinical trials. To my knowledge all of these have been published and none have been subjected to retractions or expressions of concern.	x
7. Other	☒	☐	☐	R&D directorship	In my former role as Director of Research and Development in two UK NHS Hospitals (2006-10, 2014-17), I have been involved in investigations of allegations of scientific misconduct among studies in progress and post publication.	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

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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	☒	☐	☐	Journal editorial boards	I was formerly editorial board member of various journals including BJOG (1997-2018), BMC Med Ed (2005-2012), Evidence-based Obstetrics and Gynecology (1996-2007), Reviews in Gynaecological Practice (2005-2006), Gynaecological Surgery (2004-2010). To my knowledge, of these, only BJOG published randomised clinical trials (RCTs) and it has had some RCTs retracted outside my board membership tenure.	x
2. Consultancy	☒	☐	☐			ADD x
3. Employment	☒	☐	☐			ADD x
4. Expert testimony	☒	☐	☐		I provide expert reports in medical negligence and research integrity cases for which fee is paid by instructing solicitors or parties.	ADD x

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5. Grants/grants pending	☒	☐	☐		My research is largely funded by public bodies and Charities in the UK and European Union. I have occasionally participated in research projects where pharmaceuticals (e.g. Ferring Pharmaceuticals, GSK) have contributed a grant.	×	ADD
6. Payment for lectures including service on speakers bureaus	☐	☒	☒	Ferring Pharmaceuticals; Olympus; various Universities and Societies.	I have received honoraria for speaking at meetings.	×	ADD
7. Payment for manuscript preparation	☒	☐	☐			×	ADD
8. Patents (planned, pending or issued)	☒	☐	☐			×	ADD
9. Royalties	☐	☒	☐	Taylor and Francis; Hodder Arnold; Huber.	I receive royalties on my books from publishers.	×	ADD
10. Payment for development of educational presentations	☒	☐	☐			×	ADD
11. Stock/stock options	☒	☐	☐			×	ADD
12. Travel/accommodations/meeting expenses unrelated to activities listed**	☐	☒	☒	Ferring Pharmaceuticals; Olympus; various Colleges, Universities and Societies; Public research funding bodies.	I have received honoraria and have had travel/accommodation expenses covered/reimbursed for speaking at meetings.	×	ADD

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13. Other (err on the side of full disclosure)	☐	☒	☐	HER (Health Education Research Ltd, UK)	I am a partner/director in a Partnership/Company where I offer advice on several matters including matters within medical research, manuscripts and negligence.	✕
13. Other (err on the side of full disclosure)	☐	☐	☒	Ferring Pharmaceuticals; Leo-Pharma; Alere; Ethicon; Hologic; Viforpharma; Preglem/Quintiles.	My previous UK institutions have received sponsorship for organizing educational meetings.	

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

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

Evaluation and Feedback

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