Date:		-	11/8/2021		
Your Name:			Zhou Xing		
Manuscript Title:		_	Aerosol delivery, but not intramuscular injection, of adenovirus-vectored tuberculosis vaccine induces respiratory-mucosal immunity in humans		
Mar	nuscript Number (if k	nown):	155655-INS-CMED-TR-2		
In the interest of transparency, we content of your manuscript. "Rela affected by the content of the ma		ipt. "Rela of the mar e in doubt		/interest, it is preferable that you do so.	
epic	•	nsion, you	should declare all relationships with manuf	acturers of antihypertensive medication, even if	
	em #1 below, report ne for disclosure is th			rithout time limit. For all other items, the time	
			entities with whom you have this hip or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)	
			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.	The Ca	anadian Institutes for Health rch and the Natural Sciences and eering Research Council of Canada	Click the tab key to add additional rows.	
1	present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for	The Ca	anadian Institutes for Health rch and the Natural Sciences and		
2	present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for	The Ca	anadian Institutes for Health rch and the Natural Sciences and eering Research Council of Canada  Time frame: past 36 month		

			Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	None None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None None	
6	Payment for expert testimony	None □	
7	Support for attending meetings and/or travel	None	
8	Patents planned, issued or pending	Novel COVID vaccine and method for delivery. (Inventors: B Lichty, C Ilknow, Z Xing, M Dolovich, F Smaill, K Stephenson)  US provisional application No. 63/222723, filed on July 16, 2021	
9	Participation on a Data Safety Monitoring Board or Advisory Board	None	
10	Leadership or fiduciary role in other board, society, committee or	None □	

			e all entities with whom you have this onship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
	advocacy group, paid or unpaid			
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	
Plea 🖂	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.			

Date:	11/8/2021	
Your Name:	Maria Fe C. Medina	
Manuscript Title:	Aerosol delivery, but not intramuscular injection, of adenovirus-vectored tuberculosis vaccine induces respiratory-mucosal immunity in humans	
Manuscript Number (if known):	155655-INS-CMED-TR-2	

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.

		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)
		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	Click the tab key to add additional rows.
		Time frame: past 36 month	S
2	Grants or contracts from any entity (if not indicated in item #1 above).	None	
3	Royalties or licenses	None     ■	

		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)
4	Consulting fees	None None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None None	
6	Payment for expert testimony	None None	
7	Support for attending meetings and/or travel	None     ■	
8	Patents planned, issued or pending	None None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	None     ■	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None     Non	

			e all entities with whom you have this ionship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
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	
Plea 🖂	Please place an "X" next to the following statement to indicate your agreement:     Certify that   have answered every question and have not altered the wording of any of the questions on this form.			

Date:		-	11/8/2021		
Your Name:		-	Anna Zganiacz		
Manuscript Title:		-	Aerosol delivery, but not intramuscular injection, of adenovirus-vectored tuberculosis vaccine induces respiratory-mucosal immunity in humans		
Maı	nuscript Number (if k	nown):	155655-INS-CMED-TR-2		
In the interest of transparency, we content of your manuscript. "Rela affected by the content of the ma indicate a bias. If you are in doub."  The author's relationships/activitic epidemiology of hypertension, you that medication is not mentioned.		ipt. "Rela of the mar e in doubt as/activitie nsion, you entioned i all suppor	ted" means any relation with for-profit or no nuscript. Disclosure represents a commitment about whether to list a relationship/activity, es/interests should be defined broadly. For each should declare all relationships with manufain the manuscript.	/interest, it is preferable that you do so.	
			entities with whom you have this hip or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)	
			Time frame: Since the initial planning	of the work	
			Time traine, 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.	The Ca	anadian Institutes for Health rch and the Natural Sciences and eering Research Council of Canada	Click the tab key to add additional rows.	
1	present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for	The Ca	anadian Institutes for Health rch and the Natural Sciences and	Click the tab key to add additional rows.	
2	present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for	The Ca	anadian Institutes for Health rch and the Natural Sciences and eering Research Council of Canada  Time frame: past 36 month	Click the tab key to add additional rows.	

			Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	None None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None None	
6	Payment for expert testimony	None □	
7	Support for attending meetings and/or travel	None	
8	Patents planned, issued or pending	Novel COVID vaccine and method for delivery. (Inventors: B Lichty, C Ilknow, Z Xing, M Dolovich, F Smaill, K Stephenson)  US provisional application No. 63/222723, filed on July 16, 2021	
9	Participation on a Data Safety Monitoring Board or Advisory Board	None	
10	Leadership or fiduciary role in other board, society, committee or	None □	

			e all entities with whom you have this onship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
	advocacy group, paid or unpaid			
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	
Plea 🖂	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.			

Date:	11/9/2021
Your Name:	Ruth Patricia Cusack
Manuscript Title:	Aerosol delivery, but not intramuscular injection, of adenovirus-vectored tuberculosis vaccine induces respiratory-mucosal immunity in humans
Manuscript Number (if known):	155655-INS-CMED-TR-2

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.

		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)
		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	Click the tab key to add additional rows.
		Time frame: past 36 month	S
2	Grants or contracts from any entity (if not indicated in item #1 above).	None	
3	Royalties or licenses	None     ■	

		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)
4	Consulting fees	None None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None None	
6	Payment for expert testimony	None None	
7	Support for attending meetings and/or travel	None     ■	
8	Patents planned, issued or pending	None None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	None     ■	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None     Non	

		e all entities with whom you have this ionship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
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	
Plea 🖂		e following statement to indicate your agreeme	

Date: Your Name: Manuscript Title:		11/9/2021			
		Myrna Dolovich	Myrna Dolovich		
		<u> </u>	Aerosol delivery, but not intramuscular injection, of adenovirus-vectored tuberculosis vaccine induces respiratory-mucosal immunity in humans		
Maı	nuscript Number (if k	known): 155655-INS-CMED-TR-2			
con affe indi The epic that	tent of your manuscr cted by the content of cate a bias. If you are author's relationship demiology of hyperte medication is not me	arency, we ask you to disclose all relationships/activiticipt. "Related" means any relation with for-profit or not the manuscript. Disclosure represents a commitmed in doubt about whether to list a relationship/activity os/activities/interests should be defined broadly. For ension, you should declare all relationships with manuscript in the manuscript.  all support for the work reported in this manuscript whe past 36 months.	ot-for-profit third parties whose interests may be ent to transparency and does not necessarily //interest, it is preferable that you do so.  example, if your manuscript pertains to the facturers of antihypertensive medication, even if		
		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)		
		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  The Canadian Institutes for Health Research and the Natural Sciences and Engineering Research Council of Canada	Click the tab key to add additional rows.		
		Time frame: past 36 montl	ns		
2	Grants or contracts from any entity (if not indicated in item #1 above).	None			
3	Royalties or	⊠ None			

		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)
4	Consulting fees	None None
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None
6	Payment for expert testimony	None
7	Support for attending meetings and/or travel	None
8	Patents planned, issued or pending	Novel COVID vaccine and method for delivery. (Inventors: B Lichty, C Ilknow, Z Xing, M Dolovich, F Smaill, K Stephenson)  US provisional application No. 63/222723, filed on July 16, 2021
9	Participation on a Data Safety Monitoring Board or Advisory Board	None None
10	Leadership or fiduciary role in other board, society, committee or	None

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	advocacy group, paid or unpaid		
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	
Plea 🖂	•	e following statement to indicate your agreeme ered every question and have not altered the wo	

Date:			11/9/2021		
You	r Name:		Dominik Fritz		
Manuscript Title:			Aerosol delivery, but not intramuscular injection, of adenovirus-vectored tuberculosis vaccine induces respiratory-mucosal immunity in humans		
Mai	nuscript Number (if k	(nown):	155655-INS-CMED-TR-2		
con affe indi The epic that	tent of your manuscrected by the content of cate a bias. If you are author's relationship demiology of hypertest medication is not me	ipt. "Rela of the mar e in doubt os/activitie nsion, you entioned all suppor	nted" means any relation with for-profit or no nuscript. Disclosure represents a commitment about whether to list a relationship/activity es/interests should be defined broadly. For each of the u should declare all relationships with manufin the manuscript.	/interest, it is preferable that you do so.	
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			Time frame: Since the initial planning	of the work	
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1	present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for	The Congression	anadian Institutes for Health rch and the Natural Sciences and		
2	present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for	The Congression	anadian Institutes for Health rch and the Natural Sciences and eering Research Council of Canada  Time frame: past 36 month		

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5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None
6	Payment for expert testimony	None
7	Support for attending meetings and/or travel	None
8	Patents planned, issued or pending	Novel COVID vaccine and method for delivery. (Inventors: B Lichty, C Ilknow, Z Xing, M Dolovich, F Smaill, K Stephenson)  US provisional application No. 63/222723, filed on July 16, 2021
9	Participation on a Data Safety Monitoring Board or Advisory Board	None None
10	Leadership or fiduciary role in other board, society, committee or	None

		e all entities with whom you have this onship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
	advocacy group, paid or unpaid		
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	
Plea 🖂	•	e following statement to indicate your agreeme ered every question and have not altered the wo	

Date:			11/8/2021		
You	r Name:	-	Emilio Aguirre		
Manuscript Title:			Aerosol delivery, but not intramuscular injection, of adenovirus-vectored tuberculosis vaccine induces respiratory-mucosal immunity in humans		
Mar	nuscript Number (if k	nown):	155655-INS-CMED-TR-2		
content of your manuscript. "Rela affected by the content of the ma indicate a bias. If you are in doub The author's relationships/activities			nted" means any relation with for-profit or no nuscript. Disclosure represents a commitment about whether to list a relationship/activity, es/interests should be defined broadly. For e u should declare all relationships with manufa	/interest, it is preferable that you do so.	
	em #1 below, report and for disclosure is the			ithout time limit. For all other items, the time	
			l entities with whom you have this ship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)	
			Time frame: Since the initial planning	of the work	
	All support for the present manuscript (e.g., funding, provision of study materials,	The Congression	anadian Institutes for Health rch and the Natural Sciences and		
	medical writing, article processing charges, etc.) No time limit for this item.	Engine	eering Research Council of Canada	Click the tab key to add additional rows.	
	article processing charges, etc.)  No time limit for	Engine	eering Research Council of Canada  Time frame: past 36 months		
	article processing charges, etc.)  No time limit for	⊠ Not	Time frame: past 36 months		

		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)
4	Consulting fees	None None
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None
6	Payment for expert testimony	None
7	Support for attending meetings and/or travel	None
8	Patents planned, issued or pending	Novel COVID vaccine and method for delivery. (Inventors: B Lichty, C Ilknow, Z Xing, M Dolovich, F Smaill, K Stephenson)  US provisional application No. 63/222723, filed on July 16, 2021
9	Participation on a Data Safety Monitoring Board or Advisory Board	None None
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	advocacy group, paid or unpaid		
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	
Plea 🖂	•	e following statement to indicate your agreeme ered every question and have not altered the wo	

Date:			11/11/2021		
Your Name: Manuscript Title:			Aerosol delivery, but not intramuscular injection, of adenovirus-vectored tuberculosis vaccine induces respiratory-mucosal immunity in humans		
Mar	nuscript Number (if k	nown):	155655-INS-CMED-TR-2		
In the interest of transparency, we content of your manuscript. "Rela affected by the content of the ma				·	
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			entities with whom you have this hip or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)	
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	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.		anadian Institutes for Health rch	Click the tab key to add additional rows.	
			Time frame: past 36 month	s	
2	Grants or contracts from any entity (if not indicated in item #1 above).	⊠ No	ne		
3	Royalties or licenses	⊠ No	one		

		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)
4	Consulting fees	None None
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None None
6	Payment for expert testimony	None
7	Support for attending meetings and/or travel	None
8	Patents planned, issued or pending	Novel COVID vaccine and method for delivery. (Inventors: B Lichty, C Ilknow, Z Xing, M Dolovich, F Smaill, K Stephenson)  US provisional application No. 63/222723, filed on July 16, 2021
9	Participation on a Data Safety Monitoring Board or Advisory Board	None None
10	Leadership or fiduciary role in other board, society, committee or	None

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	advocacy group, paid or unpaid		
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	
Plea 🖂	•	e following statement to indicate your agreeme ered every question and have not altered the wo	

Dat	e:	_1	11/8/2021	
You	r Name:	1_	Mangalakumari Jeyanathan	
Maı	nuscript Title:		Aerosol delivery, but not intramuscu auberculosis vaccine induces respirat	lar injection, of adenovirus-vectored ory-mucosal immunity in humans
Mai	nuscript Number (if k	nown): _1	155655-INS-CMED-TR-2	
con affe indi The epic that	tent of your manuscricted by the content of cate a bias. If you are author's relationship demiology of hypertent medication is not me	ipt. "Relate of the manu e in doubt a os/activities nsion, you s entioned in all support	ed" means any relation with for-profit or no iscript. Disclosure represents a commitment bout whether to list a relationship/activity, /interests should be defined broadly. For eshould declare all relationships with manufathe manuscript.	,
			entities with whom you have this ip or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
			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.	Researc	nadian Institutes for Health h and the Natural Sciences and ering Research Council of Canada	Click the tab key to add additional rows.
			Time frame: past 36 month	s
2	Grants or contracts from	⊠ None	2	
	any entity (if not indicated in item #1 above).			

			Specifications/Comments (e.g., if payments were made to you or to your institution)
4	Consulting fees	None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None None	
6	Payment for expert testimony	None □	
7	Support for attending meetings and/or travel	None None	
8	Patents planned, issued or pending	Novel COVID vaccine and method for delivery. (Inventors: B Lichty, C Ilknow, Z Xing, M Dolovich, F Smaill, K Stephenson)  US provisional application No. 63/222723, filed on July 16, 2021	
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10	Leadership or fiduciary role in other board, society, committee or	None     ■	

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	advocacy group, paid or unpaid			
11	Stock or stock options		None	
12	Receipt of equipment,	$\boxtimes$	None	
	materials, drugs, medical writing,			
	gifts or other services			
13	Other financial or	$\boxtimes$	None	
13	non-financial		None	
	interests			
Plea	se place an "X" next	t to the	e following statement to indicate your agreeme	ent:
$\boxtimes$	I certify that I have	answe	ered every question and have not altered the wo	ording of any of the questions on this form.

Dat	e:	-	11/8/2021	
You	r Name:	-	Michael Thompson	
Maı	nuscript Title:		Aerosol delivery, but not intramuscu tuberculosis vaccine induces respirat	
Mai	nuscript Number (if k	nown):	155655-INS-CMED-TR-2	
con affe indi The epic	tent of your manuscricted by the content of cate a bias. If you are author's relationship	ipt. "Rela of the mar e in doubt os/activition nsion, you	ted" means any relation with for-profit or no nuscript. Disclosure represents a commitment about whether to list a relationship/activity, es/interests should be defined broadly. For each should declare all relationships with manufactionships with manufactionships with manufactionships.	/interest, it is preferable that you do so.
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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)
4	Consulting fees	None None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None None	
6	Payment for expert testimony	None None	
7	Support for attending meetings and/or travel	None     ■	
8	Patents planned, issued or pending	None None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	None     ■	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None     Non	

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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	
Plea 🖂		e following statement to indicate your agreeme	

Jal	e:		11/8/2021		
You	r Name:		Sam Afkhami	_	
Ma	nuscript Title:		Aerosol delivery, but not intramuscular injection, of adenovirus-vectored tuberculosis vaccine induces respiratory-mucosal immunity in humans		
Mai	nuscript Number (if k	(nown):	155655-INS-CMED-TR-2		
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			l entities with whom you have this ship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)	
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1	All support for the		one		
	present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	Resear	anadian Institutes for Health rch and the Natural Sciences and eering Research Council of Canada	Click the tab key to add additional rows.	
	manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for	Resear	rch and the Natural Sciences and		
2	manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for	Resear	rch and the Natural Sciences and eering Research Council of Canada  Time frame: past 36 month		

		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)
4	Consulting fees	None None
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None
6	Payment for expert testimony	None
7	Support for attending meetings and/or travel	None
8	Patents planned, issued or pending	Novel COVID vaccine and method for delivery. (Inventors: B Lichty, C Ilknow, Z Xing, M Dolovich, F Smaill, K Stephenson)  US provisional application No. 63/222723, filed on July 16, 2021
9	Participation on a Data Safety Monitoring Board or Advisory Board	None None
10	Leadership or fiduciary role in other board, society, committee or	None

		e all entities with whom you have this onship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
	advocacy group, paid or unpaid		
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	
Plea 🖂	•	e following statement to indicate your agreeme ered every question and have not altered the wo	

Date	e:	-	11/8/2021	
You	r Name:		Fiona Smaill	
Mar	nuscript Title:	<u>-</u>	Aerosol delivery, but not intramuscu tuberculosis vaccine induces respirat	
Mar	nuscript Number (if k	nown):	155655-INS-CMED-TR-2	
con affe	tent of your manuscricted by the content of	ipt. "Rela of the mar		
epic	•	nsion, you		example, if your manuscript pertains to the acturers of antihypertensive medication, even if
	em #1 below, report ne for disclosure is th			ithout time limit. For all other items, the time
			entities with whom you have this hip or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
			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.	The Ca	anadian Institutes for Health rch and the Natural Sciences and eering Research Council of Canada	Click the tab key to add additional rows.
1	present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for	The Ca	anadian Institutes for Health rch and the Natural Sciences and	Click the tab key to add additional rows.
2	present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for	The Ca	anadian Institutes for Health rch and the Natural Sciences and eering Research Council of Canada  Time frame: past 36 month	Click the tab key to add additional rows.

		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)
4	Consulting fees	None None
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None None
6	Payment for expert testimony	None
7	Support for attending meetings and/or travel	None
8	Patents planned, issued or pending	Novel COVID vaccine and method for delivery. (Inventors: B Lichty, C Ilknow, Z Xing, M Dolovich, F Smaill, K Stephenson)  US provisional application No. 63/222723, filed on July 16, 2021
9	Participation on a Data Safety Monitoring Board or Advisory Board	None None
10	Leadership or fiduciary role in other board, society, committee or	None

			e all entities with whom you have this onship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)		
	advocacy group, paid or unpaid					
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			
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.						

Date:Nov 12	2/2021
Your Name:	Martin Kolb
Manuscript Title:_	Aerosol delivery, but not intramuscular injection, of adenovirus-vectored tuberculosis
vaccine induces	respiratory-mucosal immunity in humans
Manuscript numb	er (if known): Ms. 155655-INS-CMED-TR-2

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 following questions apply to the author's relationships/activities/interests as they relate to the <u>current manuscript only</u>.

The author's relationships/activities/interests should be <u>defined broadly</u>. 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.

		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)
		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	
		Time frame: past	36 months
2	Grants or contracts from any entity (if not indicated in item #1 above).	Boehringer Ingelheim Pieris Roche	Research funding for preclinical work As above Research funding for clinical projects
3	Royalties or licenses	None	
4	Consulting fees	Boehringer Ingelheim Roche	

5	Payment or honoraria for lectures, presentations,	Horizon Cipla Abbvie Belerophon Algernon CSL Behring Novartis Boehringer Ingelheim	
	speakers bureaus, manuscript writing or educational events	Roche	
6	Payment for expert testimony	Roche	Court testimony
7	Support for attending meetings and/or travel	None	
8	Patents planned, issued or pending	None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	Covance United Therapeutics	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	ERJ	Chief Editor allowance
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	

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

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

Date:	11/8/2021
Your Name:	Gail Gauvreau
Manuscript Title:	Aerosol delivery, but not intramuscular injection, of adenovirus-vectored tuberculosis vaccine induces respiratory-mucosal immunity in humans
Manuscript Number (if known):	155655-INS-CMED-TR-2

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.

		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)
		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 None	Click the tab key to add additional rows.
		Time frame: past 36 month	s
2	Grants or contracts from any entity (if not indicated in item #1 above).	AstraZeneca Biohaven Pharmaceuticals Novartis Pharmaceuticals Genentech Inc	Payments made to institution Payments made to institution Payments made to institution Payments made to institution
3	Royalties or licenses	None     ■	

4 Consulting fees None AstraZeneca P	Payments made to me Payments made to me
AstraZeneca P.	
	Dayments made to me
Biohaven Pharmaceuticals P	Payments made to me
Novartis Pharmaceuticals P	Payments made to me
Sterna Biologicals P.	Payments made to me
Certior Consulting P.	Payments made to me
5 Payment or None honoraria for	
lectures, AstraZeneca P	Payments made to me
	Payments made to me
speakers Genentech Inc P	Payments made to me
bureaus, manuscript writing or educational events	
6 Payment for expert testimony None	
7 Support for attending Support for Support for attending Support for Support for attending Support for Suppo	
meetings and/or travel	
li avei	
8 Patents planned,   None	
issued or	
pending	
9 Participation on a Data Safety None	
Monitoring	
Board or	
Advisory Board	
10 Leadership or Fiduciary role in None	
other board,	
society,	
committee or	
advocacy group, paid or unpaid	

			e all entities with whom you have this ionship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
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  None		
Plea 🖂	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.			

Date:	10/11/2021
Your Name:	Imran Satia
Manuscript Title:	Aerosol delivery, but not intramuscular injection, of adenovirus-vectored tuberculosis vaccine induces respiratory-mucosal immunity in humans
Manuscript Number (if known):	155655-INS-CMED-TR-2

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 following questions apply to the author's relationships/activities/interests as they relate to the <u>current</u> <u>manuscript only</u>.

The author's relationships/activities/interests should be <u>defined broadly</u>. 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.

		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)
		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	
		Time frame: past	36 months
2	Grants or contracts from any entity (if not indicated in item #1 above).	None	
3	Royalties or licenses	None	

Sample of the content of the conte	4	Consulting fees	None	
lectures, presentations, speakers bureaus, manuscript writing or educational events  6 Payment for expert testimony  7 Support for attending meetings and/or travel  8 Patents planned, issued or pending  9 Participation on a Data Safety Monitoring Board or Advisory Board  10 Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid  11 Stock or stock options  12 Receipt of equipment, materials, drugs, medical writing, gifts or other services  13 Other financial or non-  None    None				
lectures, presentations, speakers bureaus, manuscript writing or educational events  6 Payment for expert testimony  7 Support for attending meetings and/or travel  8 Patents planned, issued or pending  9 Participation on a Data Safety Monitoring Board or Advisory Board  10 Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid  11 Stock or stock options  12 Receipt of equipment, materials, drugs, medical writing, gifts or other services  13 Other financial or non-  None    None				
speakers bureaus, manuscript writing or educational events  6	5		None	
manuscript writing or educational events 6 Payment for expert testimony 7 Support for attending meetings and/or travel  8 Patents planned, issued or pending 9 Participation on a Data Safety Monitoring Board or Advisory Board 10 Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid 11 Stock or stock options 12 Receipt of equipment, materials, drugs, medical writing, gifts or other services 13 Other financial or non-    None				
educational events  Payment for expert testimony  Support for attending meetings and/or travel  Patents planned, issued or pending  Participation on a Data Safety Monitoring Board or Advisory Board  Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid  Stock or stock options  Receipt of equipment, materials, drugs, medical writing, gifts or other services  None				
Farticipation on a Data Safety Monitoring Board or Advisory Board  Leadership or fluciary role in other board, society, committee or advocacy group, paid or unpaid  Receipt of equipment, materials, drugs, medical writing, gifts or other services  Mone  None				
testimony  Support for attending meetings and/or travel  Because of the poard, society, committee or advocacy group, paid or unpaid  Receipt of equipment, materials, drugs, medical writing, gifts or other services  Support for attending meetings and or and	_		Nava	
Support for attending meetings and/or travel  8 Patents planned, issued or pending  9 Participation on a Data Safety Monitoring Board or Advisory Board  10 Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid  11 Stock or stock options  12 Receipt of equipment, materials, drugs, medical writing, gifts or other services  13 Other financial or non-  15 Support for attending Mone  Mone	ь		None	
meetings and/or travel		•		
8 Patents planned, issued or pendingNone	7		None	
pending  Participation on a Data Safety Monitoring Board or Advisory Board  Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid  Stock or stock options  None  Receipt of equipment, materials, drugs, medical writing, gifts or other services  None				
pending  Participation on a Data Safety Monitoring Board or Advisory Board  Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid  Stock or stock options  None  Receipt of equipment, materials, drugs, medical writing, gifts or other services  None				
9 Participation on a Data Safety Monitoring Board or Advisory Board  10 Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid  11 Stock or stock options  12 Receipt of equipment, materials, drugs, medical writing, gifts or other services  13 Other financial or non-  None  None  None  None  None  None	8		None	
Safety Monitoring Board or Advisory Board  10 Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid  11 Stock or stock options  12 Receipt of equipment, materials, drugs, medical writing, gifts or other services  13 Other financial or non-  None  None  None  None		pending		
Safety Monitoring Board or Advisory Board  10 Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid  11 Stock or stock options  12 Receipt of equipment, materials, drugs, medical writing, gifts or other services  13 Other financial or non-  None  None  None  None				
Advisory Board  Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid  Stock or stock options  Receipt of equipment, materials, drugs, medical writing, gifts or other services  None  None  None  None  None  None  None  None  None	9		None	
10 Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid  11 Stock or stock options  12 Receipt of equipment, materials, drugs, medical writing, gifts or other services  13 Other financial or non-  None  None  None  None  None				
in other board, society, committee or advocacy group, paid or unpaid  Stock or stock options  Receipt of equipment, materials, drugs, medical writing, gifts or other services  None  None  None  None  None  None  None		•		
committee or advocacy group, paid or unpaid  11 Stock or stock options  None  None  None  None  None  Other financial or non-  None  None	10		None	
group, paid or unpaid  Stock or stock options  None  Receipt of equipment, materials, drugs, medical writing, gifts or other services  Other financial or non-  None  None				
11 Stock or stock options  Receipt of equipment, materials, drugs, medical writing, gifts or other services  13 Other financial or non-  None  None  None  None				
materials, drugs, medical writing, gifts or other services  13 Other financial or non- None None	11	Stock or stock options	None	
materials, drugs, medical writing, gifts or other services  13 Other financial or non- None None				
materials, drugs, medical writing, gifts or other services  13 Other financial or non- None None				
writing, gifts or other services  13 Other financial or nonNoneNone	12		None	
services  13 Other financial or non- None None				
13 Other financial or non- NoneNone				
	13		None	
		financial interests		

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

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

			191102 210020011210		
Date	e:		11/8/2021		
Your Name:			Paul M O'Byrne		
Manuscript Title:			Aerosol delivery, but not intramuscular injection, of adenovirus-vectored tuberculosis vaccine induces respiratory-mucosal immunity in humans		
Man	nuscript Number (if	known):	155655-INS-CMED-TR-2		
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.			ot-for-profit third parties whose interests may be nt to transparency and does not necessarily		
epid		ension, you		example, if your manuscript pertains to the acturers of antihypertensive medication, even if	
	em #1 below, report ne for disclosure is th			ithout time limit. For all other items, the time	
			entities with whom you have this hip or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)	
			Time frame: Since the initial planning	of the work	
	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing	The C Resear	anadian Institutes for Health rch and the Natural Sciences and eering Research Council of Canada	Click the tab key to add additional rows.	
charges, etc.)  No time limit for this item.					
			Time frame: past 36 month	S	
2	Grants or contracts from	□ No	ne		
	any entity (if not	AstraZe		Grant: institutional payment	
	indicated in item #1 above).	Novarti Biohave		Grant: institutional payment Grant: institutional payment	
	0.0000/.	Merck	511	Grant: institutional payment  Grant: institutional payment	
		GSK		Grant: institutional payment	
3	Royalties or licenses	⊠ No	one		

		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)
4	Consulting fees	□ None  AstraZeneca GSK Covis Teva	Personal payment Personal payment Personal payment Personal payment
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	□ None  AstraZeneca Covis Cipla GSK Menarini	Personal payment Personal payment Personal payment Personal payment Personal payment
6	Payment for expert testimony	None	
7	Support for attending meetings and/or travel	None	
8	Patents planned, issued or pending	None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None     ■	

			e all entities with whom you have this ionship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
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	
Plea 🖂	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.			

Date:	11/8/2021
Your Name:	Anna Dvorkin-Gheva
Manuscript Title:	Aerosol delivery, but not intramuscular injection, of adenovirus-vectored tuberculosis vaccine induces respiratory-mucosal immunity in humans
Manuscript Number (if known):	155655-INS-CMED-TR-2

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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.

		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)
		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     ■	Click the tab key to add additional rows.
		Time frame: past 36 month	S
2	Grants or contracts from any entity (if not indicated in item #1 above).	None	
3	Royalties or licenses	None     ■	

		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)
4	Consulting fees	None None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None None	
6	Payment for expert testimony	None None	
7	Support for attending meetings and/or travel	None     ■	
8	Patents planned, issued or pending	None None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	None     ■	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None     Non	

			e all entities with whom you have this ionship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
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	
Plea ⊠	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.			

Date:	11/8/2021
Your Name:	Karen Howie
Manuscript Title:	Aerosol delivery, but not intramuscular injection, of adenovirus-vectored tuberculosis vaccine induces respiratory-mucosal immunity in humans
Manuscript Number (if known):	155655-INS-CMED-TR-2

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.

		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)
		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 None	Click the tab key to add additional rows.
		Time frame: past 36 month	S
2	Grants or contracts from any entity (if not indicated in item #1 above).	None	
3	Royalties or licenses	None     ■	

		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)
4	Consulting fees	None None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None None	
6	Payment for expert testimony	None None	
7	Support for attending meetings and/or travel	None     ■	
8	Patents planned, issued or pending	None None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	None     ■	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None     Non	

			e all entities with whom you have this ionship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
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	
Plea 🖂	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.			

Date:	11/8/2021
Your Name:	Richard Silver
Manuscript Title:	Aerosol delivery, but not intramuscular injection, of adenovirus-vectored tuberculosis vaccine induces respiratory-mucosal immunity in humans
Manuscript Number (if known):	155655-INS-CMED-TR-2

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.

		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)
		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     ■	Click the tab key to add additional rows.
		Time frame: past 36 month	S
2	Grants or contracts from any entity (if not indicated in item #1 above).	None	
3	Royalties or licenses	None     ■	

		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)
4	Consulting fees	None None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	None None	
6	Payment for expert testimony	None None	
7	Support for attending meetings and/or travel	None     ■	
8	Patents planned, issued or pending	None None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	None     ■	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	None     Non	

		e all entities with whom you have this ionship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
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	
Plea ⊠	-	e following statement to indicate your agreeme ered every question and have not altered the wo	

## **TREND Statement Checklist**

Paper	Item	Descriptor		Reported?	
Section/ Topic	No			Pg#	
Title and Abst	ract				
Title and	1	Information on how unit were allocated to interventions	+		
Abstract		Structured abstract recommended	+		
		Information on target population or study sample	+		
Introduction					
Background	2	Scientific background and explanation of rationale	+		
_		Theories used in designing behavioral interventions	+		
Methods	•				
Participants	3	Eligibility criteria for participants, including criteria at different levels in			
		recruitment/sampling plan (e.g., cities, clinics, subjects)	+		
		Method of recruitment (e.g., referral, self-selection), including the	İ		
		sampling method if a systematic sampling plan was implemented	+		
		Recruitment setting			
		Settings and locations where the data were collected	+		
Interventions	4	Details of the interventions intended for each study condition and how			
		and when they were actually administered, specifically including:	+		
		Content: what was given?	+		
		<ul> <li>Delivery method: how was the content given?</li> </ul>	+		
		<ul> <li>Unit of delivery: how were the subjects grouped during delivery?</li> </ul>	+		
		Deliverer: who delivered the intervention?	+		
		Setting: where was the intervention delivered?	+		
		<ul> <li>Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?</li> </ul>	+		
		<ul> <li>Time span: how long was it intended to take to deliver the intervention to each unit?</li> </ul>			
		<ul> <li>Activities to increase compliance or adherence (e.g., incentives)</li> </ul>	+		
Objectives	5	Specific objectives and hypotheses	+		
Outcomes	6	Clearly defined primary and secondary outcome measures	+		
		<ul> <li>Methods used to collect data and any methods used to enhance the quality of measurements</li> </ul>	+		
		<ul> <li>Information on validated instruments such as psychometric and biometric properties</li> </ul>			
Sample Size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	+		
Assignment Method	8	<ul> <li>Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)</li> </ul>	+		
		Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	+		
		Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	+		

# **TREND Statement Checklist**

Blinding (masking)	9	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed.		
Unit of Analysis	10	Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	+	
		If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis)	+	
Statistical Methods	11	Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data	+	
		Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis	+	
		Methods for imputing missing data, if used		
		Statistical software or programs used	+	
Results				
Participant flow	12	<ul> <li>Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended)</li> </ul>	+	
		<ul> <li>Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study</li> </ul>	+	
		<ul> <li>Assignment: the numbers of participants assigned to a study condition</li> </ul>	+	
		<ul> <li>Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention</li> </ul>	+	
		<ul> <li>Follow-up: the number of participants who completed the follow-up or did not complete the follow-up (i.e., lost to follow-up), by study condition</li> </ul>	+	
		<ul> <li>Analysis: the number of participants included in or excluded from the main analysis, by study condition</li> </ul>	+	
		Description of protocol deviations from study as planned, along with reasons	+	
Recruitment	13	Dates defining the periods of recruitment and follow-up	+	
Baseline Data	14	Baseline demographic and clinical characteristics of participants in each study condition	+	
		Baseline characteristics for each study condition relevant to specific disease prevention research	+	
		Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	+	
		Comparison between study population at baseline and target population of interest	+	
Baseline equivalence	15	Data on study group equivalence at baseline and statistical methods used to control for baseline differences	+	

## **TREND Statement Checklist**

Numbers analyzed	16	Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible	+
		<ul> <li>Indication of whether the analysis strategy was "intention to treat" or, if not, description of how non-compliers were treated in the analyses</li> </ul>	+
Outcomes and estimation	17	<ul> <li>For each primary and secondary outcome, a summary of results for each estimation study condition, and the estimated effect size and a confidence interval to indicate the precision</li> </ul>	+
		Inclusion of null and negative findings	+
		Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	
Ancillary analyses	18	Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	+
Adverse events	19	<ul> <li>Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals)</li> </ul>	+
DISCUSSION			
Interpretation	20	<ul> <li>Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study</li> </ul>	+
		Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	+
		Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	+
		Discussion of research, programmatic, or policy implications	+
Generalizability	21	<ul> <li>Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other contextual issues</li> </ul>	+
Overall Evidence	22	General interpretation of the results in the context of current evidence and current theory	+

*From:* Des Jarlais, D. C., Lyles, C., Crepaz, N., & the Trend Group (2004). Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND statement. *American Journal of Public Health*, 94, 361-366. For more information, visit: <a href="http://www.cdc.gov/trendstatement/">http://www.cdc.gov/trendstatement/</a>