

#### **Instructions**

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## Identifying information.

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

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

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

Wells



Section 1. Ider	ntifying Information	
1. Given Name (First Nam J. Michael	ne) 2. Surname (Last Name) Wells	3. Date 13-September-2018
4. Are you the correspond	ding author? Yes No	
5. Manuscript Title Elevated Circulating M/	MP-9 and Increased Exacerbation Risk in COPD: Re	esults from SPIROMICS and COPDGene
6. Manuscript Identifying 123614-INS-CMED-1	Number (if you know it)	
Section 2.		
The \	Work Under Consideration for Publication	
Did you or your institution any aspect of the submitte statistical analysis, etc.)? Are there any relevant o	ed work (including but not limited to grants, data moni	party (government, commercial, private foundation, etc.) for toring board, study design, manuscript preparation,
Section 3. Polo	yant financial activities and id-d	
Place a check in the app of compensation) with e	entities as described in the instructions. Use one li c. You should report relationships that were <b>prese</b>	ou have financial relationships (regardless of amount ine for each entity; add as many lines as you need by
Section 4. Intell	ectual Property Patents & Copyrights	
Do you have any patent	s, whether planned, pending or issued, broadly re	elevant to the work?



Section 5.	Relationships not covered above	
Are there other r potentially influe	relationships or activities that readers could perceive to have influenced, or that give the appearance of encing, what you wrote in the submitted work?	
Yes, the following relationships/conditions/circumstances are present (explain below):  No other relationships/conditions/circumstances that present a potential conflict of interest		
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Dr. Wells has not	thing to disclose.	

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Parker 1



Section 1. Identifying Inform	mation	
Given Name (First Name)     Margaret	2. Surname (Last Name) Parker	3. Date 13-September-2018
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Amit Gaggar and J. Michael Wells
5. Manuscript Title Elevated Circulating MMP-9 and Incre	ased Exacerbation Risk in C	OPD: Results from SPIROMICS and COPDGene
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Section 3. Relevant financia	al activities outside the	submitted work.
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Intellectual Prop	erty Patents & Copyri	ghts
Do you have any patents, whether pla	nned, pending or issued, b	roadly relevant to the work? Yes V No



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Oster



Section 1. Identifying Inform	nation	
Given Name (First Name) Robert	2. Surname (Last Name) Oster	3. Date 13-September-2018
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Amit Gaggar and J. Michael Wells
5. Manuscript Title Elevated Circulating MMP-9 and Increa	sed Exacerbation Risk in C	OPD: Results from SPIROMICS and COPDGene
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Section 2. The Work Under C	onsideration for Publi	cation
Did you or your institution <b>at any time</b> rece any aspect of the submitted work (including statistical analysis, etc.)? Are there any relevant conflicts of inter-	g but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ata monitoring board, study design, manuscript preparation,
Section 3. Relevant financial	activities outside the	submitted work.
of compensation) with entities as descr	ribed in the instructions. Uport relationships that we	nether you have financial relationships (regardless of amount se one line for each entity; add as many lines as you need by re present during the 36 months prior to publication.
Sortion 4		
Section 4. Intellectual Prope	rty Patents & Copyri	ghts
Do you have any patents, whether plan	nned, pending or issued, b	roadly relevant to the work? Yes Vo

Oster



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Dr. Oster has no	othing to disclose.

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Oster 3



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Bowler



Section 1.	dentifying Inform	ation		eka meserbia
1. Given Name (First Russ	Name)	2. Surname (Last Name) Bowler		3. Date 13-September-2018
4. Are you the corres	ponding author?	Yes ✓ No	Corresponding Author's Nan Amit Gaggar and J. Micha	
5. Manuscript Title Elevated Circulating	g MMP-9 and Increase	ed Exacerbation Risk in C	OPD: Results from SPIROMIC	CS and COPDGene
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6 4 2				
		nsideration for Publi		
Did you or your institu any aspect of the sub statistical analysis, etc	mitted work (including	ve payment or services fron but not limited to grants, d	n a third party (government, cor ata monitoring board, study de:	nmercial, private foundation, etc.) for sign, manuscript preparation,
Are there any relev	ant conflicts of intere	st? Yes Vo		
Section 3.	Relevant financial a	activities outside the	submitted work.	
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Bowler



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Dransfield 1



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1. Given Name (First Name) Mark	2. Surname (Last Name) Dransfield	3. Date 13-September-2018
4. Are you the corresponding author?	Yes  ✓ No	Corresponding Author's Name Amit Gaggar and J. Michael Wells
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patent

Bhatt 1



Section 1. Identifying Info	rmation	
Given Name (First Name) Surya	2. Surname (Last Name) Bhatt	3. Date 13-September-2018
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Amit Gaggar and J. Michael Wells
5. Manuscript Title Elevated Circulating MMP-9 and Incre	eased Exacerbation Risk in C	OPD: Results from SPIROMICS and COPDGene
6. Manuscript Identifying Number (if you 123614-INS-CMED-1	know it)	
	Consideration for Publiceive payment or services from	cation  a third party (government, commercial, private foundation, etc.) for
	ing but not limited to grants, d	ata monitoring board, study design, manuscript preparation,
And there any relevant commets of the	rest. Tes Vino	
Section 3. Relevant financia	al activities outside the	submitted work.
Place a check in the appropriate boxe of compensation) with entities as des	es in the table to indicate wh cribed in the instructions. U	nether you have financial relationships (regardless of amount lse one line for each entity; add as many lines as you need by
clicking the "Add +" box. You should Are there any relevant conflicts of int	report relationships that we	re present during the 36 months prior to publication.
Section 4. Intellectual Prop	erty Patents & Copyri	ghts
Do you have any patents, whether pl	anned, pending or issued, b	roadly relevant to the work? Yes Vo

Bhatt



Section 5.	Relationships not covered above
	relationships or activities that readers could perceive to have influenced, or that give the appearance of encing, what you wrote in the submitted work?
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patent

Cho 1



Section 1. Identifying Infor	mation	
Given Name (First Name)     Michael	2. Surname (Last Name) Cho	3. Date 13-September-2018
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Amit Gaggar and J. Michael Wells
5. Manuscript Title Elevated Circulating MMP-9 and Incre	ased Exacerbation Risk in C	COPD: Results from SPIROMICS and COPDGene
6. Manuscript Identifying Number (if you 123614-INS-CMED-1	know it)	
Section 2. The Work Under	Consideration for Publ	ication
		m a third party (government, commercial, private foundation, etc.) for data monitoring board, study design, manuscript preparation,
Are there any relevant conflicts of inte	erest? Yes 🗸 No	
Section 3. Relevant financia	al activities outside the	submitted work.
of compensation) with entities as des	cribed in the instructions. Ureport relations that we	hether you have financial relationships (regardless of amount Use one line for each entity; add as many lines as you need by ere <b>present during the 36 months prior to publication</b> .
,		
Section 4. Intellectual Prop	erty Patents & Copyr	ights
Do you have any patents, whether pla	anned, pending or issued, b	oroadly relevant to the work? Yes No

Cho



Section 5.	Relationships not covered above
	relationships or activities that readers could perceive to have influenced, or that give the appearance of encing, what you wrote in the submitted work?
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✓ No other rela	ationships/conditions/circumstances that present a potential conflict of interest
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Kim 1



Section 1. Identifying Infor	mation	
Given Name (First Name)  Victor	2. Surname (Last Name) Kim	3. Date 13-September-2018
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Amit Gaggar and J. Michael Wells
5. Manuscript Title Elevated Circulating MMP-9 and Incre	ased Exacerbation Risk in C	COPD: Results from SPIROMICS and COPDGene
6. Manuscript Identifying Number (if you 123614-INS-CMED-1	know it)	
123014 INS CMED 1		
Section 2. The Work Under	Consideration for Publ	ication
any aspect of the submitted work (including		n a third party (government, commercial, private foundation, etc.) for lata monitoring board, study design, manuscript preparation,
statistical analysis, etc.)? Are there any relevant conflicts of inte	erest? Yes 🗸 No	
Section 3. Relevant financia	al activities outside the	submitted work.
		hether you have financial relationships (regardless of amount Use one line for each entity; add as many lines as you need by
clicking the "Add +" box. You should r Are there any relevant conflicts of inte	A STATE OF THE STA	ere present during the 36 months prior to publication.
Section 4. Intellectual Prop	erty Patents & Copyr	ights
Do you have any patents, whether pla	anned, pending or issued, b	proadly relevant to the work? Yes V No

Kim 2



Section 5.	
100	Relationships not covered above
Are there other r potentially influe	relationships or activities that readers could perceive to have influenced, or that give the appearance of encing, what you wrote in the submitted work?
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### 4. Intellectual Property.

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Curtis



Section 1.	Identifying Inforn	nation	
1. Given Name (Fi Jeffrey	rst Name)	2. Surname (Last Na Curtis	me) 3. Date 13-September-2018
4. Are you the cor	responding author?	☐ Yes ✓ No	Corresponding Author's Name Amit Gaggar and J. Michael Wells
5. Manuscript Title Elevated Circulat		sed Exacerbation Ris	k in COPD: Results from SPIROMICS and COPDGene
6. Manuscript Ider 123614-INS-CME	ntifying Number (if you kr ED-1	now it)	
Section 2.	The Work Under C	onsideration for F	Publication
any aspect of the s statistical analysis,	ubmitted work (including	g but not limited to gra	s from a third party (government, commercial, private foundation, etc.) for nts, data monitoring board, study design, manuscript preparation, No
Section 3.	Relevant financial	activities outside	the submitted work.
of compensation clicking the "Add	he appropriate boxes i ) with entities as descr	in the table to indica ibed in the instructio port relationships the	the submitted work.  It is whether you have financial relationships (regardless of amount ons. Use one line for each entity; add as many lines as you need by at were present during the 36 months prior to publication.  No
Section 4.	Intellectual Proper	rty Patents & Co	pyrights
Do you have any			ed, broadly relevant to the work? Yes No

Curtis



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patent

Martinez



Section 1. Identifying Inform	nation	
Given Name (First Name)  Fernando	2. Surname (Last Name) Martinez	3. Date 13-September-2018
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name
5. Manuscript Title Elevated Circulating MMP-9 and Increa	ised Exacerbation Risk in C	Amit Gaggar and J. Michael Wells  OPD: Results from SPIROMICS and COPDGene
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Did you or your institution <b>at any time</b> rece any aspect of the submitted work (including statistical analysis, etc.)? Are there any relevant conflicts of inter	g but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for at a monitoring board, study design, manuscript preparation,
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Do you have any patents, whether plan		



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Dr. Martinez has	nothing to disclose.

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Section 1. Identifying Inform	nation	
Given Name (First Name)  Robert	2. Surname (Last Name) Paine	3. Date 13-September-2018
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Amit Gaggar and J. Michael Wells
5. Manuscript Title Elevated Circulating MMP-9 and Increa	ised Exacerbation Risk in C	OPD: Results from SPIROMICS and COPDGene
6. Manuscript Identifying Number (if you k 123614-INS-CMED-1	now it)	
Continue 2		
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Did you or your institution <b>at any time</b> rece any aspect of the submitted work (including statistical analysis, etc.)? Are there any relevant conflicts of inter	g but not limited to grants, da	n a third party (government, commercial, private foundation, etc.) for ata monitoring board, study design, manuscript preparation,
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Do you have any patents, whether plan		



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Dr. Paine has no	thing to disclose.

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O'Neal



Section 1. Identi	fying Information	
1. Given Name (First Name) Wanda	2. Surname (Last Na O'Neal	me) 3. Date 13-September-2018
4. Are you the corresponding	ng author? Yes V	Corresponding Author's Name Amit Gaggar and J. Michael Wells
5. Manuscript Title Elevated Circulating MMI	P-9 and Increased Exacerbation Risl	k in COPD: Results from SPIROMICS and COPDGene
6. Manuscript Identifying N 123614-INS-CMED-1	umber (if you know it)	
Section 2. The W	ork Under Consideration for P	ublication
Did you or your institution a any aspect of the submitted statistical analysis, etc.)?  Are there any relevant co	work (including but not limited to grain	s from a third party (government, commercial, private foundation, etc.) for nts, data monitoring board, study design, manuscript preparation,
Section 3. Releva	nt financial activities outside	the cultimitted 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 <b>present during the 36 months prior to publication</b> .  Are there any relevant conflicts of interest? Yes V No		
Section 4. Intelle	ctual Property Patents & Co	nyrights
	whether planned, pending or issue	



Section 5.	Relationships not covered above
Are there other re potentially influe	elationships or activities that readers could perceive to have influenced, or that give the appearance of encing, what you wrote in the submitted work?
Yes, the follow	wing relationships/conditions/circumstances are present (explain below):
✓ No other rela	tionships/conditions/circumstances that present a potential conflict of interest
At the time of ma On occasion, jour	anuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. rnals may ask authors to disclose further information about reported relationships.
Section 6.	Disclosure Statement
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O'Neal



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Labaki



Section 1. Identifying Inform	mation	
Given Name (First Name)  Wassim	2. Surname (Last Name) Labaki	3. Date 13-September-2018
4. Are you the corresponding author?	Yes ✓ No	Corresponding Author's Name Amit Gaggar and J. Michael Wells
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	rest. Tes V No	
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Section 4. Intellectual Prope	erty Patents & Copyri	ghts
Do you have any patents, whether plan	nned, pending or issued, br	roadly relevant to the work? Yes V No



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patent

Kaner



Section 1. Identifying Inform	nation	
Given Name (First Name) Robert	2. Surname (Last Name) Kaner	3. Date 13-September-2018
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Amit Gaggar and J. Michael Wells
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Do you have any patents, whether plan	nned, pending or issued, br	oadly relevant to the work? Yes No



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At the time of ma On occasion, jou	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.		
Sections			
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Section 1.	Identifying Inform	nation	
1. Given Name (Fi Igor	irst Name)	2. Surname (Last Name) Barjaktarevic	3. Date 13-September-2018
4. Are you the cor	responding author?	☐ Yes ✓ No	Corresponding Author's Name Amit Gaggar and J. Michael Wells
5. Manuscript Titl Elevated Circula		sed Exacerbation Risk in C	COPD: Results from SPIROMICS and COPDGene
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Do you have any	patents, whether plan	nned, pending or issued, b	roadly relevant to the work? Yes No



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Based on the abo	ove disclosures, this form will automatically generate a disclosure statement, which will appear in the box
Dr. Barjaktarevic	has nothing to disclose.

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Barjaktarevic



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Other: Anything not covered under the previous three boxes

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

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

Silverman 1



Section 1.	dentifying Informat	ion	
1. Given Name (First Edwin		. Surname (Last Name) ilverman	3. Date 13-September-2018
4. Are you the corres	ponding author?	Yes ✓ No	Corresponding Author's Name Amit Gaggar and J. Michael Wells
5. Manuscript Title Elevated Circulatin	g MMP-9 and Increased	Exacerbation Risk in	COPD: Results from SPIROMICS and COPDGene
6. Manuscript Identif 123614-INS-CMED-	ying Number (if you know 1	it)	
Section 2.	he Work Under Cons	sideration for Publ	lication
any aspect of the sub statistical analysis, etc	mitted work (including bu	t not limited to grants, o	m a third party (government, commercial, private foundation, etc.) for data monitoring board, study design, manuscript preparation,
Section 3.			
K	elevant financial act		
of compensation) v	vith entities as described	d in the instructions. l	hether you have financial relationships (regardless of amount Use one line for each entity; add as many lines as you need by ere <b>present during the 36 months prior to publication</b> .
	ant conflicts of interest?		the present during the 50 months prior to publication.
Section 4.	ntellectual Property	Patents & Copyr	ights
Do you have any pa	atents, whether planned	d, pending or issued, b	proadly relevant to the work? Yes V No



Section 5.	Deletionships not severed above
	Relationships not covered above
Are there other in potentially influence	relationships or activities that readers could perceive to have influenced, or that give the appearance of encing, what you wrote in the submitted work?
Yes, the follo	wing relationships/conditions/circumstances are present (explain below):
✓ No other rela	ationships/conditions/circumstances that present a potential conflict of interest
At the time of m On occasion, jou	anuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. Irnals may ask authors to disclose further information about reported relationships.
Section 6.	Disclosure Statement
Based on the above below.	ove disclosures, this form will automatically generate a disclosure statement, which will appear in the box
Dr. Silverman ha	as nothing to disclose.

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Silverman



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patent

Crapo



Section 1. Identifying Info	ormation	
Given Name (First Name)  James	2. Surname (Last Name) Crapo	3. Date 13-September-2018
4. Are you the corresponding author?	Yes V No	Corresponding Author's Name Amit Gaggar and J. Michael Wells
5. Manuscript Title Elevated Circulating MMP-9 and Inc	reased Exacerbation Risk in C	OPD: Results from SPIROMICS and COPDGene
6. Manuscript Identifying Number (if yo 123614-INS-CMED-1	u know it)	
Section 2. The Work Unde	r Consideration for Publi	cation
Did you or your institution at any time rany aspect of the submitted work (include statistical analysis, etc.)?  Are there any relevant conflicts of in	ling but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ata monitoring board, study design, manuscript preparation,
Section 3. Balance 6		
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 <b>present during the 36 months prior to publication</b> .  Are there any relevant conflicts of interest? Yes V No		
Section 4. Intellectual Pro	perty Patents & Copyrig	ghts
Do you have any patents, whether p	lanned, pending or issued, br	roadly relevant to the work? Yes No



Section 5.	Relationships not covered above
Are there other repotentially influen	ationships or activities that readers could perceive to have influenced, or that give the appearance of cing, what you wrote in the submitted work?
	ing relationships/conditions/circumstances are present (explain below): onships/conditions/circumstances that present a potential conflict of interest
On occasion, jourr	nuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements hals may ask authors to disclose further information about reported relationships.
Section 6.	Disclosure Statement
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Barr 1



Section 1. Identifying	Information	
1. Given Name (First Name) Graham	2. Surname (Last Name) Barr	3. Date 13-September-2018
4. Are you the corresponding auth	or?	Corresponding Author's Name Amit Gaggar and J. Michael Wells
5. Manuscript Title Elevated Circulating MMP-9 and	d Increased Exacerbation Risk in Co	OPD: Results from SPIROMICS and COPDGene
6. Manuscript Identifying Number 123614-INS-CMED-1	(if you know it)	
Did you or your institution at any ti	ncluding but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ta monitoring board, study design, manuscript preparation,
Section 3. Relevant fin	ancial activities outside the s	ubmitted work.
of compensation) with entities a	as described in the instructions. Us ould report relationships that wer	ether you have financial relationships (regardless of amount se one line for each entity; add as many lines as you need by e present during the 36 months prior to publication.
Section 4. Intellectual	Property Patents & Copyric	ıhts
Do you have any patents, wheth	ner planned, pending or issued, br	oadly relevant to the work? Yes Vo



Section 5.	Deletionali
	Relationships not covered above
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Woodruff



Section 1. Identifyi	ng Information					
Given Name (First Name)  Prescott	2. Surname (Last Name) Woodruff	3. Date 13-September-2018				
4. Are you the corresponding at	uthor? Yes V No	Corresponding Author's Name Amit Gaggar and J. Michael Wells				
5. Manuscript Title Elevated Circulating MMP-9	and Increased Exacerbation Risk in Co	OPD: Results from SPIROMICS and COPDGene				
6. Manuscript Identifying Numb	per (if you know it)					
Section 2. The Work	Under Consideration for Public	cation				
Did you or your institution <b>at an</b> any aspect of the submitted wor statistical analysis, etc.)? Are there any relevant conflic	k (including but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ta monitoring board, study design, manuscript preparation,				
Section 3. Relevant	financial activities outside the s	ubmitted work.				
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Section 4. Intellectu	al Property Patents & Copyric	ghts				
Do you have any patents, wh	ether planned, pending or issued, br	oadly relevant to the work? Yes Vo				

Woodruff



Section 5.	Relationships not covered above
Are there other r potentially influe	elationships or activities that readers could perceive to have influenced, or that give the appearance of encing, what you wrote in the submitted work?
- W	wing relationships/conditions/circumstances are present (explain below): tionships/conditions/circumstances that present a potential conflict of interest
At the time of ma On occasion, jou	anuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements rnals may ask authors to disclose further information about reported relationships.
Section 6.	Disclosure Statement
Based on the abo	ove disclosures, this form will automatically generate a disclosure statement, which will appear in the box
Dr. Woodruff ha	s nothing to disclose.

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1

patent

Castaldi



Section 1. Identifying Info	rmation	
Given Name (First Name)  Peter	2. Surname (Last Name) Castaldi	3. Date 13-September-2018
4. Are you the corresponding author?	☐ Yes ✓ No	Corresponding Author's Name Amit Gaggar and J. Michael Wells
5. Manuscript Title Elevated Circulating MMP-9 and Incre	eased Exacerbation Risk in C	OPD: Results from SPIROMICS and COPDGene
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The Work Under	<b>Consideration for Publi</b>	cation
Did you or your institution <b>at any time</b> re any aspect of the submitted work (includi statistical analysis, etc.)?  Are there any relevant conflicts of interesting the state of the state	ing but not limited to grants, da	a third party (government, commercial, private foundation, etc.) for ata monitoring board, study design, manuscript preparation,
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Do you have any patents, whether pla	anned, pending or issued, b	roadly relevant to the work? Yes V No



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Dr. Castaldi has i	nothing to disclose.

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Castaldi



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patent



Section 1. Identifying Infor	mation	
Given Name (First Name)     Amit	2. Surname (Last Name) Gaggar	3. Date 13-September-2018
4. Are you the corresponding author?	✓ Yes No	
5. Manuscript Title Elevated Circulating MMP-9 and Incre	ased Exacerbation Risk in COPD: Resul	ts from SPIROMICS and COPDGene
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## STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1	
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	6-7	
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	9-10	
Objectives	3	State specific objectives, including any prespecified hypotheses	10	
Methods				
Study design	4	Present key elements of study design early in the paper	20-23	At end of manuscript per journal style
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	20	
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants	20	
		(b) Cohort study—For matched studies, give matching criteria and number of exposed and unexposed  Case-control study—For matched studies, give matching criteria and the number of controls per case	n/a	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers.  Give diagnostic criteria, if applicable	20-23	
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	21-22	
Bias	9	Describe any efforts to address potential sources of bias	20-23	
Study size	10	Explain how the study size was arrived at	35	CONSORT Diagram

Quantitative	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which	22-23	
variables		groupings were chosen and why		
Statistical	12	(a) Describe all statistical methods, including those used to control for confounding	22-23	
methods		(b) Describe any methods used to examine subgroups and interactions	22-23	
		(c) Explain how missing data were addressed	22-23	Complete case analysis
		(d) Cohort study—If applicable, explain how loss to follow-up was addressed	n/a	
		Case-control study—If applicable, explain how matching of cases and controls was addressed		
		Cross-sectional study—If applicable, describe analytical methods taking account of sampling		
		strategy		
		$(\underline{e})$ Describe any sensitivity analyses	n/a	
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined	11 & 35	
		for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed		
		(b) Give reasons for non-participation at each stage	35	CONSORT Diagram
		(c) Consider use of a flow diagram	35	CONSORT Diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on	11 & 41	Table 1
		exposures and potential confounders		
		(b) Indicate number of participants with missing data for each variable of interest	n/a	Complete case analysis
		(c) Cohort study—Summarise follow-up time (eg, average and total amount)	12-13	
Outcome data	15*	Cohort study—Report numbers of outcome events or summary measures over time	12-14	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	n/a	
		Cross-sectional study—Report numbers of outcome events or summary measures	n/a	
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision	11-14; tables	
		(eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were		
		included		
		(b) Report category boundaries when continuous variables were categorized	11-14; tables	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time	39	Figure 4 (p39)
		period		

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Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11-14, tables	
Discussion				
Key results	18	Summarise key results with reference to study objectives	15	
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss	18	
		both direction and magnitude of any potential bias		
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of	19	
		analyses, results from similar studies, and other relevant evidence		
Generalisability	21	Discuss the generalisability (external validity) of the study results	15-19	
Other informati	on			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the	7-8	
		original study on which the present article is based		

<sup>\*</sup>Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.