

ICMJE Form for Disclosure of Potential Conflicts of Interest

Instructions

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Mahmoud	2. Surname (Last Name) Abou Alaiwa	3. Date 18-June-2018
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Michael J. Welsh
5. Manuscript Title Ivacaftor-Induced Sweat Chloride Reductions Correlate with Increases in Airway Surface Liquid pH in Cystic Fibrosis		
6. Manuscript Identifying Number (if you know it) 121468-INS-RG-1		

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Are there any relevant conflicts of interest? ☐ Yes ☒ No

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Dr. Abou Alaiwa has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)
Janice

2. Surname (Last Name)
Launspach

3. Date
18-June-2018

4. Are you the corresponding author? ☐ Yes ☒ No Corresponding Author's Name
Michael J. Welsh

5. Manuscript Title
Ivacaftor-Induced Sweat Chloride Reductions Correlate with Increases in Airway Surface Liquid pH in Cystic Fibrosis

6. Manuscript Identifying Number (if you know it)
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Section 1. Identifying Information

1. Given Name (First Name) Brenda	2. Surname (Last Name) Grogan	3. Date 18-June-2018
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Michael J. Welsh
5. Manuscript Title Ivacaftor-Induced Sweat Chloride Reductions Correlate with Increases in Airway Surface Liquid pH in Cystic Fibrosis		
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Dr. Grogan has nothing to disclose.

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Section 1. Identifying Information

1. Given Name (First Name)
Suzanne

2. Surname (Last Name)
Carter

3. Date
18-June-2018

4. Are you the corresponding author?

☐ Yes ☒ No

Corresponding Author's Name
Michael J. Welsh

5. Manuscript Title

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Dr. Carter has nothing to disclose.

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1. Given Name (First Name)

Joseph

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Zabner

3. Date

18-June-2018

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☐ Yes

☒ No

Corresponding Author's Name

Michael J. Welsh

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)
David

2. Surname (Last Name)
Stoltz

3. Date
20-June-2018

4. Are you the corresponding author? ☐ Yes ☒ No Corresponding Author's Name
Michael J. Welsh

5. Manuscript Title
Ivacaftor-Induced Sweat Chloride Reductions Correlate with Increases in Airway Surface Liquid pH in Cystic Fibrosis

6. Manuscript Identifying Number (if you know it)
121468-INS-RG-1

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? ☐ Yes ☒ No

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Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☐ Yes ☒ No

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Section 5.

Relationships not covered above

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Evaluation and Feedback

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Pradeep	2. Surname (Last Name) Singh	3. Date 20-June-2018
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Michael J. Welsh
5. Manuscript Title Ivacaftor-Induced Sweat Chloride Reductions Correlate with Increases in Airway Surface Liquid pH in Cystic Fibrosis		
6. Manuscript Identifying Number (if you know it) 121468-INS-RG-1		

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Are there any relevant conflicts of interest? ☐ Yes ☒ No

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ICMJE Form for Disclosure of Potential Conflicts of Interest

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Section 6. Disclosure Statement

Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.

Dr. Singh has nothing to disclose.

Evaluation and Feedback

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Edward	2. Surname (Last Name) McKone	3. Date 19-June-2018
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Michael J. Welsh
5. Manuscript Title Ivacaftor induced changes in sweat chloride correlate with Airway surface liquid pH in cystic fibrosis.		
6. Manuscript Identifying Number (if you know it) 121468-INS-RG-1		

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Are there any relevant conflicts of interest? ☒ Yes ☐ No

If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" button to add a row. Excess rows can be removed by pressing the "X" button.

Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Vertex	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? ☒ Yes ☐ No

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Novartis	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Proteostasis	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
PTC	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

ICMJE Form for Disclosure of Potential Conflicts of Interest

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Gilead	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☐ Yes ☒ No

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Dr. McKone reports grants and personal fees from Vertex, during the conduct of the study; personal fees from Novartis, Proteostasis and PTC, grants from Gilead, outside the submitted work; .

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Michael

2. Surname (Last Name)

Welsh

3. Date

18-June-2018

4. Are you the corresponding author?

☒ Yes ☐ No

5. Manuscript Title

Ivacaftor-Induced Sweat Chloride Reductions Correlate with Increases in Airway Surface Liquid pH in Cystic Fibrosis

6. Manuscript Identifying Number (if you know it)

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —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 <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
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
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (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 (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*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.