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ICMJE Form for Disclosure of Potential Conflicts of Interest

Instructions

The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form is designed to be completed electronically and stored electronically. It contains programming that allows appropriate data display. Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information. The form is in six parts.

1. Identifying information.

2. The work under consideration for publication.

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4. Intellectual Property.

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

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Non-Financial Support: Examples include drugs/equipment supplied by the entity, travel paid by the entity, writing assistance, administrative support, etc.

Other: Anything not covered under the previous three boxes

Pending: The patent has been filed but not issued

Issued: The patent has been issued by the agency

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

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Section 1. Identifying Information

1. Given Name (First Name): Amir
2. Surname (Last Name): Zeki
3. Date: 23-April-2020

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Nicholas J. Kenyon

5. Manuscript Title: L-Arginine Supplementation in Severe Asthma

6. Manuscript Identifying Number (if you know it):

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (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

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	
NIH	☑	☐	☐	☐	Dr Kenyon's R01 NIH grant	×

ADD

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Dr. Kenyon's NIH R01grant to conduct this clinical trial, during the conduct of the study; .

Evaluation and Feedback

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Section 1. Identifying Information

1. Given Name (First Name): Lisa
2. Surname (Last Name): Franzi
3. Date: 27-April-2020

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Nicholas Kenyon

5. Manuscript Title: L-Arginine Supplementation in Severe Asthma

6. Manuscript Identifying Number (if you know it): 137777-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

ADD

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Dr. Franzi has nothing to disclose.

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Section 1. Identifying Information

1. Given Name (First Name): Shu-Yi
2. Surname (Last Name): Liao
3. Date: 23-April-2020

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Nicholas Kenyon

5. Manuscript Title: L-Arginine Supplementation in Severe Asthma

6. Manuscript Identifying Number (if you know it): ms. 137777-INS-RG-1

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Section 1. Identifying Information

1. Given Name (First Name): Michael
2. Surname (Last Name): Sa
3. Date: 28-April-2020

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Nicholas J. Kenyon

5. Manuscript Title: L-Arginine Supplementation in Severe Asthma

6. Manuscript Identifying Number (if you know it): 137777-INS-RG-1

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NIH	☑	☐	☐	☐		×

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Section 1. Identifying Information

1. Given Name (First Name): Lihong
2. Surname (Last Name): Qi
3. Date: 23-April-2020

4. Are you the corresponding author? ☐ Yes ☑ No Corresponding Author's Name

5. Manuscript Title: L-Arginine Supplementation in Severe Asthma

6. Manuscript Identifying Number (if you know it)

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Dr. Qi reports grants from NIH, during the conduct of the study.

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Section 1. Identifying Information

1. Given Name (First Name): Yao
2. Surname (Last Name): Li
3. Date: 23-April-2020

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Nicholas Kenyon

5. Manuscript Title: L-Arginine Supplementation in Severe Asthma

6. Manuscript Identifying Number (if you know it):

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (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 1. Identifying Information

1. Given Name (First Name): Angela
2. Surname (Last Name): Linderholm
3. Date: 23-April-2020

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Nicholas Kenyon,

5. Manuscript Title: L-Arginine Supplementation in Severe Asthma

6. Manuscript Identifying Number (if you know it): 137777-INS-RG-1

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

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Dr. Linderholm has nothing to disclose.

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Section 1. Identifying Information

1. Given Name (First Name): Nicholas
2. Surname (Last Name): Kenyon
3. Date: 23-April-2020

4. Are you the corresponding author? [✔] Yes [ ] No

5. Manuscript Title: L-Arginine Supplementation in Severe Asthma

6. Manuscript Identifying Number (if you know it): 137777-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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Are there any relevant conflicts of interest? [ ] Yes [✔] No

ADD

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. Kenyon has nothing to disclose.

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Section 1. Identifying Information

1. Given Name (First Name) Ce..\e.-s+c
2. Surnar e y. ast Name) K \" \e_r
3. Date 5/28/2020.

4. Are you the corresponding author? 0 Yes 0 No

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J- - A 6 L'-.1 p/e_m,e_J\ oJ LC"'- 1I} Severe Asthma:

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Section 1. Identifying Information

1. Given Name (First Name): Megan
2. Surname (Last Name): Showalter
3. Date: 27-April-2020

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Nicholas J Kenyon

5. Manuscript Title: L-Arginine Supplementation in Severe Asthma

6. Manuscript Identifying Number (if you know it): 137777-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	
NIH	☑	☐	☐	☐		×

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Dr. Showalter reports grants from NIH, during the conduct of the study; .

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For grants you have received for work outside the submitted work, you should disclose support ONLY from entities that could be perceived to be affected financially by the published work, such as drug companies, or foundations supported by entities that could be perceived to have a financial stake in the outcome. Public funding sources, such as government agencies, charitable foundations or academic institutions, need not be disclosed. For example, if a government agency sponsored a study in which you have been involved and drugs were provided by a pharmaceutical company, you need only list the pharmaceutical company.

4. Intellectual Property.

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

5. Relationships not covered above.

Use this section to report other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work.

Definitions.

Entity: government agency, foundation, commercial sponsor, academic institution, etc.

Grant: A grant from an entity, generally [but not always] paid to your organization

Personal Fees: Monies paid to you for services rendered, generally honoraria, royalties, or fees for consulting , lectures, speakers bureaus, expert testimony, employment, or other affiliations

Non-Financial Support: Examples include drugs/equipment supplied by the entity, travel paid by the entity, writing assistance, administrative support, etc.

Other: Anything not covered under the previous three boxes

Pending: The patent has been filed but not issued

Issued: The patent has been issued by the agency

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

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

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name): Zachary
2. Surname (Last Name): Kons
3. Date: 23-April-2020

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Nicholas J. Kenyon

5. Manuscript Title: L-Arginine Supplementation in Severe Asthma

6. Manuscript Identifying Number (if you know it): 137777-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

ADD

Section 3. Relevant financial activities outside the submitted work.

Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were **present during the 36 months prior to publication**.

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

ADD

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

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

☐ Yes, the following relationships/conditions/circumstances are present (explain below):

☑ No other relationships/conditions/circumstances that present a potential conflict of interest

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.

Section 6. Disclosure Statement

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

Generate Disclosure Statement

Mr. Kons has nothing to disclose.

Evaluation and Feedback

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

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Instructions

The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form is designed to be completed electronically and stored electronically. It contains programming that allows appropriate data display. Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information. The form is in six parts.

1. Identifying information.

2. The work under consideration for publication.

This section asks for information about the work that you have submitted for publication. The time frame for this reporting is that of the work itself, from the initial conception and planning to the present. The requested information is about resources that you received, either directly or indirectly (via your institution), to enable you to complete the work. Checking "No" means that you did the work without receiving any financial support from any third party -- that is, the work was supported by funds from the same institution that pays your salary and that institution did not receive third-party funds with which to pay you. If you or your institution received funds from a third party to support the work, such as a government granting agency, charitable foundation or commercial sponsor, check "Yes".

3. Relevant financial activities 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): Oliver
2. Surname (Last Name): Fiehn
3. Date: 23-April-2020

4. Are you the corresponding author? ☐ Yes ☑ No

Corresponding Author's Name: Nicholas Kenyon

5. Manuscript Title: L-Arginine Supplementation in Severe Asthma

6. Manuscript Identifying Number (if you know it):

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (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

ADD

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

ADD

Section 4. Intellectual Property -- Patents & Copyrights

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Section 6. Disclosure Statement

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Generate Disclosure Statement

Dr. Fiehn has nothing to disclose.

Evaluation and Feedback

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

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	3, abstract
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3, abstract
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5, introduction
	2b	Specific objectives or hypotheses	5, introduction
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	19, methods
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	1, supplement
Participants	4a	Eligibility criteria for participants	19, methods; 1 supplement
	4b	Settings and locations where the data were collected	19, methods
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	20, methods
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7, results
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	21, results
	7b	When applicable, explanation of any interim analyses and stopping guidelines	4, supplement
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	20, methods
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	20, methods
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	20, methods
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	20, methods

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	19, methods
	11b	If relevant, description of the similarity of interventions	19, methods
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	21, methods 4, supplement
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	21, methods
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	7-10, results
	13b	For each group, losses and exclusions after randomisation, together with reasons	7, results Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7, results
	14b	Why the trial ended or was stopped	7, results
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	7-10, results
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	7-10, results
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	8-10, results
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	12, results
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	15,17-18, discussion
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	18,discussion
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	12, discussion
Other information			
Registration	23	Registration number and name of trial registry	NCT01841281
Protocol	24	Where the full trial protocol can be accessed, if available	FDA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	NIH, Jarrow Pharma.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.