

ICMJE Form for Disclosure of Potential Conflicts of Interest

Instructions

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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

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Nuhoda	2. Surname (Last Name) Aldarij	3. Date 16-August-1995
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Emma James
5. Manuscript Title Immunogenicity, safety and efficacy of a standalone universal influenza vaccine, FLU-v: A randomised, double-blind, placebo-controlled, single-centre phase IIb trial conducted in healthy adults as part of the EU-funded UNISEC		
6. Manuscript Identifying Number (if you know it) 		

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

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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
EU	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	UNISEC is funded by the EU

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 6. Disclosure Statement

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Dr. Aldarij reports grants from EU, outside the submitted work; .

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Section 1. Identifying Information

1. Given Name (First Name)
Hubert

2. Surname (Last Name)
Niesters

3. Date
05-June-2019

4. Are you the corresponding author?

☐ Yes ☒ No

Corresponding Author's Name
Dr. Olga Pleguezuelos

5. Manuscript Title

"Immunogenicity, safety and efficacy of a standalone universal influenza vaccine, FLU-v: A randomised, double-blind, placebo-controlled, single-centre phase IIb trial conducted in healthy adults as part of the EU-funded UNISEC project.."

6. Manuscript Identifying Number (if you know it)

M19-0735

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Dr. Niesters has nothing to disclose.

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ICMJE

INTERNATIONAL COMMITTEE of
MEDICAL JOURNAL EDITORS

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

PAUL

2. Surname (Last Name)

GRUENEVELD

3. Date

04-06-2019

4. Are you the corresponding author?

☐ Yes

☒ No

5. Manuscript Title

Immunogenicity, Safety, efficacy of a standalone

6. Manuscript Identifying Number (if you know it)

M 19-0735

Universal Influenza
Vaccine

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Section 1. Identifying Information

1. Given Name (First Name)
Olga

2. Surname (Last Name)
Pleguezuelos

3. Date
04-June-2019

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

5. Manuscript Title
Immunogenicity, safety and efficacy of a standalone universal influenza vaccine, FLU-v: A randomised, double-blind, placebo-controlled, single-centre phase IIb trial conducted in healthy adults as part of the EU-funded UNISEC project

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Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
European Framework 7	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	The European Framework 7 provided funding for the Consortium (UNISEC)

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Dr. Pleguezuelos reports grants from European Framework 7, during the conduct of the study; .

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04-June-2019

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☒ No

Corresponding Author's Name

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Dr. Hak reports grants from EU, during the conduct of the study; .

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4. Intellectual Property.

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

5. Relationships not covered above.

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Pending: The patent has been filed but not issued

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

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Gregory	2. Surname (Last Name) Stoloff	3. Date 07-June-2019
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Matt Memoli
5. Manuscript Title Immunogenicity, safety and efficacy of a standalone universal influenza vaccine, FLU-v: A randomised, double-blind, placebo-controlled, single-centre phase IIb trial conducted in healthy adults as part of the EU-funded UNISEC project.		
6. Manuscript Identifying Number (if you know it) M19-0735		

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
EU FP 7 Programme	<input checked="" type="checkbox"/>	<input 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

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☒ 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.

ICMJE Form for Disclosure of Potential Conflicts of Interest

Patent?	Pending?	Issued?	Licensed?	Royalties?	Licensee?	Comments
Peptide Sequences and Compositions (Influenza)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Owned by the Sponsor I am employed by and I am an inventor

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):
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I own shares in the Sponsor company

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Section 6. Disclosure Statement

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Dr. Stoloff reports grants from EU FP 7 Programme, during the conduct of the study; In addition, Dr. Stoloff has a patent Peptide Sequences and Compositions (Influenza) issued and I own shares in the Sponsor company.

ICMJE Form for Disclosure of Potential Conflicts of Interest

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)
Demy

2. Surname (Last Name)
Idema

3. Date
07-June-2019

4. Are you the corresponding author?

☐ Yes ☒ No

Corresponding Author's Name
Dr. Olga Pleguezuelos

5. Manuscript Title
Immunogenicity, safety and efficacy of a standalone universal influenza vaccine, FLU-v: A randomised, double-blind, placebo-controlled, single-centre phase IIb trial conducted in healthy adults as part of the EU-funded UNISEC project.

6. Manuscript Identifying Number (if you know it)

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

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Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
EU	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	UNISEC is funded by the EU

Section 3. Relevant financial activities outside the submitted work.

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

Section 4. Intellectual Property -- Patents & Copyrights

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Ms. Idema reports grants from EU, during the conduct of the study.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Ana

2. Surname (Last Name)

Fernandez

3. Date

06-October-2019

4. Are you the corresponding author?

☒ Yes ☐ No

5. Manuscript Title

Immunogenicity, safety and efficacy of a standalone universal influenza vaccine, FLU-v: A randomised, double-blind, placebo-controlled, single-centre phase IIb trial conducted in healthy adults as part of the EU-funded UNISEC project

6. Manuscript Identifying Number (if you know it)

M19-0735

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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
European Commission DG-Research, European Member States	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Within the UNISEC project (FP7-Health No. 602012)

Section 3. Relevant financial activities outside the submitted work.

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Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Fernandez reports grants from European Comission DG-Research, European Member States, during the conduct of the study; .

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Joep

2. Surname (Last Name)

Dille

3. Date

03-July-2019

4. Are you the corresponding author?

☐ Yes

☒ No

Corresponding Author's Name

5. Manuscript Title

Immunogenicity, safety and efficacy of a standalone universal influenza vaccine, FLU-v: A randomised, double-blind, placebo-controlled, single-centre phase IIb trial conducted in healthy adults as part of the EU-funded UNISEC project

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Are there any relevant conflicts of interest?

☐ Yes

☒ No

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☐ Yes

☒ No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work?

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ICMJE Form for Disclosure of Potential Conflicts of Interest

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Dr. Dille 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)
Henderik W.

2. Surname (Last Name)
Frijlink

3. Date
05-July-2019

4. Are you the corresponding author?

☐ Yes ☒ No

Corresponding Author's Name
Olga Pleguezuelos

5. Manuscript Title
Immunogenicity, safety and efficacy of a standalone universal influenza vaccine, FLU-v: A randomised, double-blind, placebo-controlled, single-centre phase IIb trial conducted in healthy adults as part of the EU-funded UNISEC project.

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

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

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Dr. Frijlink has nothing to disclose.

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

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Olav

2. Surname (Last Name)

Hungnes

3. Date

10-July-2019

4. Are you the corresponding author?

☐ Yes

☒ No

Corresponding Author's Name

Olga Pleguezuelos

5. Manuscript Title

Immunogenicity, safety and efficacy of a standalone universal influenza vaccine, FLU-v: A randomised, double-blind, placebo-controlled, single-centre phase IIb trial conducted in healthy adults as part of the EU-funded UNISEC project.

6. Manuscript Identifying Number (if you know it)

M19-0735

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Are there any relevant conflicts of interest?

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☒ No

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☐ Yes

☒ No

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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Md Atiqul

2. Surname (Last Name)

Islam

3. Date

01-July-2019

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☐ Yes

☒ No

Corresponding Author's Name

Dr Olga Pleguezuelos

5. Manuscript Title

Immunogenicity, safety and efficacy of a standalone universal influenza vaccine, FLU-v: A randomised, double-blind, placebo-controlled, single-centre phase IIb trial conducted in healthy adults as part of the EU-funded UNISEC

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Dr. Islam 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) Emma	2. Surname (Last Name) James	3. Date 27-August-2019
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Olga Pleguezuelos
5. Manuscript Title Immunogenicity, safety and efficacy of a standalone universal influenza vaccine, FLU-v: A randomised, double-blind, placebo-controlled, single-centre phase IIb trial conducted in healthy adults as part of the EU-funded UNISEC project		
6. Manuscript Identifying Number (if you know it) M19-0735		

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

Section 4. Intellectual Property -- Patents & Copyrights

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I am an employee of SEEK, the company that developed the vaccine

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Dr. James reports and I am an employee of SEEK, the company that developed the vaccine.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Lisbeth Meyer	2. Surname (Last Name) Næss	3. Date 28-August-2019
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Olga Pleguezuelos
5. Manuscript Title "Immunogenicity, safety and efficacy of a standalone universal influenza vaccine, FLU-v: A randomised, double-blind, placebo-controlled, single-centre phase IIb trial conducted in healthy adults as part of the EU-funded UNISEC project"		
6. Manuscript Identifying Number (if you know it) M19-0735		

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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
European union (UNISEC project)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Section 3. Relevant financial activities outside the submitted work.

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Dr. Næss reports grants from European union (UNISEC project), during the conduct of the study; .

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Fredrik	2. Surname (Last Name) Oftung	3. Date 28-August-2019
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Olga Plegezuelos
5. Manuscript Title Immunogenicity, safety and efficacy of a standalone universal influenza vaccine, FLU-v: A randomised, double-blind, placebo-controlled, single-centre phase IIb trial conducted in healthy adults as part of the EU-funded UNISEC project.		
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Are there any relevant conflicts of interest? ☒ Yes ☐ No

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Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
EU commission supported project UNISEC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the 36 months prior to submission of the work. This should include all monies from sources with relevance to the submitted work, not just monies from the entity that sponsored the research. Please note that your interactions with the work's sponsor that are outside the submitted work should also be listed here. If there is any question, it is usually better to disclose a relationship than not to do so.

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

4. 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



ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1.

Identifying Information

1. Given Name (First Name)

Sofie

2. Surname (Last Name)

de Groen

3. Date

02-02-2020

4. Are you the corresponding author?

☐

Yes

☐

No

5. Manuscript Title

Immunogenicity, safety and efficacy of a standalone universal influenza vaccine, FLU-v: A randomised, double-blind, placebo-controlled, single-centre phase IIb trial conducted in healthy adults as part of the EU-funded UNISEC project.

6. Manuscript Identifying Number (if you know it)

M19-0735

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

Evaluation and Feedback

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