

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)

Joan

2. Surname (Last Name)

Hecht

3. Date

08-March-2016

4. Are you the corresponding author?

Yes No

5. Manuscript Title

Long-Term Pioglitazone Treatment for Patients with NASH and Prediabetes or T2DM: A Randomized Controlled Trial

6. Manuscript Identifying Number (if you know it)

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Section 4. Intellectual Property -- Patents & Copyrights

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Romina	2. Surname (Last Name) Lomonaco	3. Date 08-March-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Kenneth Cusi
5. Manuscript Title Long-Term Pioglitazone Treatment for Patients with NASH and Prediabetes or T2DM: A Randomized Controlled Trial		
6. Manuscript Identifying Number (if you know it) M15-1774		

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Section 1. Identifying Information

1. Given Name (First Name) Carolina	2. Surname (Last Name) Ortiz-Lopez	3. Date 09-March-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Kenneth Cusi, MD
5. Manuscript Title Long-Term Pioglitazone Treatment for Patients with NASH and Prediabetes or T2DM: A Randomized Controlled Trial		
6. Manuscript Identifying Number (if you know it) M15-1774		

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Section 1. Identifying Information

1. Given Name (First Name)
Kenneth

2. Surname (Last Name)
Cusi

3. Date
28-April-2016

4. Are you the corresponding author? Yes No

5. Manuscript Title
"Long-Term Pioglitazone Treatment for Patients with NASH and Prediabetes or T2DM: A Randomized Controlled Trial"

6. Manuscript Identifying Number (if you know it)
M15-1774

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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
Takeda Pharmaceuticals NA	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Provided pioglitazone and placebo
Novartis	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Research study
Janssen Research & Development, LLC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Research study
Eli Lilly and Company	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Consultant
Tobira Therapeutics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Consultant
Pfizer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Consultant

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Dr. Cusi reports non-financial support from Takeda Pharmaceuticals NA (kindly provided pioglitazone or placebo tablets for the trial), grant support from Novartis and Janssen Research & Development, LLC, and other from Eli Lilly and Company, Tobira Therapeutics, and Pfizer, outside the submitted work.

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Fernando

2. Surname (Last Name)

Bril

3. Date

29-April-2016

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Kenneth Cusi

5. Manuscript Title

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Dr. Brill 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)

NICOLAS

2. Surname (Last Name)

MUSI

3. Date

4-28-16

4. Are you the corresponding author?

Yes

No

5. Manuscript Title

Long Term Proglitazone Treatment for Patients Re Diabetes or Prediabetes, a randomized controlled trial

6. Manuscript Identifying Number (if you know it)

M15-1774

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

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

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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) Amy	2. Surname (Last Name) Webb	3. Date 04-May-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Cusi
5. Manuscript Title Long-Term Pioglitazone Treatment for Patients with NASH and Prediabetes or T2DM: A Randomized Controlled Trial		
6. Manuscript Identifying Number (if you know it) M15-1774		

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

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

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Dr. Webb 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)
Celia

2. Surname (Last Name)
Darland

3. Date
04-May-2016

4. Are you the corresponding author?

Yes No

Corresponding Author's Name
Kenneth Cusi, MD

5. Manuscript Title

Long Term Pioglitazone Treatment for Patients with NASH and Prediabetes or T2DM: A Randomized Controlled Trial

6. Manuscript Identifying Number (if you know it)

M15-1774

Section 2. The Work Under Consideration for Publication

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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

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Celia Darland 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)
Beverly

2. Surname (Last Name)
Orsak

3. Date
04-May-2016

4. Are you the corresponding author? Yes No

5. Manuscript Title
"Long-Term Pioglitazone Treatment for Patients with NASH and Prediabetes or T2DM: A Randomized Controlled Trial"

6. Manuscript Identifying Number (if you know it)
M15-1774

Section 2. The Work Under Consideration for Publication

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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

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Paola	2. Surname (Last Name) Portillo-Sanchez	3. Date 14-May-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Dr. Kenneth Cusi
5. Manuscript Title Long-Term Pioglitazone Treatment for Patients with NASH and Prediabetes or T2DM: A Randomized Controlled Trial		
6. Manuscript Identifying Number (if you know it) M15-1774		

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Dr. Portillo-Sanchez 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)
Lou Jean

2. Surname (Last Name)
Hardies

3. Date
29-April-2016

4. Are you the corresponding author?

Yes No

Corresponding Author's Name
Kenneth Cusi, MD

5. Manuscript Title

Long-Term Pioglitazone Treatment for Patients with NASH and Prediabetes or T2DM: A Randomized Controlled Trial

6. Manuscript Identifying Number (if you know it)

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Are there any relevant conflicts of interest? Yes No

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

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?

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Section 6. Disclosure Statement

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Evaluation and Feedback

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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.

This section asks about your financial relationships with entities in the bio-medical arena that could be perceived to influence, or that give the appearance of potentially influencing, what you wrote in the submitted work. You should disclose interactions with ANY entity that could be considered broadly relevant to the work. For example, if your article is about testing an epidermal growth factor receptor (EGFR) antagonist in lung cancer, you should report all associations with entities pursuing diagnostic or therapeutic strategies in cancer in general, not just in the area of EGFR or lung cancer.

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

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Section 1. Identifying Information

1. Given Name (First Name) Fermin	2. Surname (Last Name) Tio	3. Date 24-May-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Kenneth Cusi
5. Manuscript Title Long-Term Pioglitazone Treatment for Patients with NASH and Prediabetes or T2DM: A Randomized Controlled Trial		
6. Manuscript Identifying Number (if you know it) M15-1774		

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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

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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