

## 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.

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.

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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.

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) Blake	2. Surname (Last Name) Cameron	3. Date 08-November-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Crowley
5. Manuscript Title Clinical Outcomes of Metformin Use in Populations with Chronic Kidney Disease, Congestive Heart Failure, or Chronic Liver Disease: A Systematic Review		
6. Manuscript Identifying Number (if you know it) M16-1901		

### 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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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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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

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

Dr. Cameron 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)  
Matthew

2. Surname (Last Name)  
Crowley

3. Date  
31-October-2016

4. Are you the corresponding author?  Yes  No

5. Manuscript Title  
Clinical Outcomes of Metformin Use in Populations with Chronic Kidney Disease, Congestive Heart Failure, or Chronic Liver Disease: A Systematic Review

6. Manuscript Identifying Number (if you know it)  
M16-1901

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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
Veterans Administration QUERI	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Dr. Crowley reports grants from Veterans Administration QUERI, during the conduct of the study.

### Evaluation and Feedback

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# VA EVIDENCE-BASED SYNTHESIS PROGRAM

## GUIDANCE ON CONFLICTS OF INTEREST



The purpose of this guidance is to protect the scientific integrity and credibility of work produced by the VA Evidence-based Synthesis Program (ESP), and to promote objectivity and minimize potential risk of bias in the evidence synthesis process by collecting and addressing perceptions of conflicts of interest (COIs), perceived or actual.

Individuals may play different roles on ESP projects, thus requiring a tailored approach to managing COIs that takes into account the level of responsibility in framing the questions, application of methods, and making judgments and conclusions in the report.

### DEFINITIONS OF ROLES ON ESP PROJECTS:

- a. ESP Core Team (includes the ESP Director)
- b. Operational Partners
- c. Technical Expert Panel
- d. Invited Peer Reviewers

#### ESP Core Team

The Core Team includes anyone who participates meaningfully in any of the following steps of the evidence synthesis process, which includes:

- a. Decisions on the scope of the review
- b. Design and execution of the literature search strategy
- c. Decisions on which studies shall be included or excluded from the evidence report or other product (screening of abstracts and full-text studies)
- d. Abstraction of information from eligible studies
- e. Analyses of the evidence
- f. Grading or rating the quality of studies and body of evidence
- g. Writing or editing any portion of the evidence report or other product.

Decisions about who comprises the Core Team for COI purposes should be made based on the participation in one or more tasks as listed above. *A COI Declaration is required for these individuals.*

The ESP Center Director is responsible for identifying and assembling the Core Team and maintains responsibility for collecting and assessing COI disclosures from team members.

#### Operational Partners (OP)

The Operational Partner is a VHA health system policymaker who will be utilizing the review to inform clinical practice or policy issues at the national level. The OP has either nominated/requested the review on the topic, or has signed on to sponsor the nomination that may have been requested by another VHA

*\*adapted from the "VA CONFLICT OF INTEREST, CONFIDENTIALITY AND NON-DISCLOSURE RULES", "AHRQ EPC Policy on Financial and Non-financial Interests" and the "ICMJE Form for Disclosure of Potential Conflicts of Interest" form.*



office. Operational Partners are consulted to better understand the contextual factors underlying the initial request, determine the scope of the review/approval protocol, identify technical experts and peer reviewers, and review the draft report. They may also provide consultation on dissemination strategies once the report is completed. The OPs do not participate directly in writing or editing any portion of the draft or final ESP report and thus the report is not intended to represent the judgments or conclusions of the OPs. *A COI Declaration is not collected from the Operational Partner.*

### **Technical Expert Panel (TEP) member**

Technical Experts provide clinical and methodological expertise to the ESP Core Team and are recruited to guide topic development; refine key questions; assure relevance of the topic to VA/VHA; and are invited to review the draft report. The TEP members do not participate directly in writing or editing any portion of the draft or final ESP report and thus the report is not intended to represent the judgments or conclusions of the TEP. *A COI Declaration is collected when individual TEP members are invited to review the draft report.*

### **Invited Peer Reviewers**

Peer reviewers provide written feedback on the draft report. The ESP strives to identify independent, unbiased experts to review ESP reports. Peer reviewers do not participate directly in writing or editing any portion of the draft or final ESP report. De-identified reviewer comments and their disposition are included as an appendix in the final report. *A COI Declaration is required for these individuals.*

## **TIME PERIOD FOR COI DECLARATION**

The ESP recommends a 12 month “look back” period in reporting potential COIs, and to report any potential relationships for the next 12 months. If any member of the Core Team develops a new relationship during their participation in the project, they must update and resubmit a disclosure form within 7 days. This may affect his or her role in the project.

## **MANAGEMENT OF COI**

ESP Directors will assess potential COIs for their proposed Core Team on each project, and they shall be described when requesting topics for assignment. Once an assignment is made, a COI Declaration Form will be required for each Core Team member to be submitted to the ESP Coordinating Center (CC) within 10 days. New members of the team must submit a COI before working on the review.

Appearance of conflicts will be managed by the (CC) and reported to HSR&D/QUERI. The CC will evaluate the appearance of a conflict and determine whether or not the interest would give the appearance of influence on the outcome of the review and if the individual may participate in the review. When necessary, the QUERI Director may grant a waiver to allow participation in the review.

COI Declaration for TEP members and invited peer reviewers will be collected and evaluated by the CC when invited to review the draft report.

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# CONFLICT OF INTEREST DECLARATION ESP CORE TEAM



**Topic:** Safety of metformin for patients with contraindications

### Instructions

Complete a COI Declaration for each ESP Core Team member and return copies to the ESP Coordinating Center within 10 calendar days of topic assignment.

The Conflict of Interest Declaration must be signed and returned prior to the start of the evidence synthesis project. Core Team Members having a conflict of interest with a particular review must declare it prior to initiating work on the review. Prior to the review, an action plan to mitigate the appearance of influence must be created by the ESP Center and approved by QUERI.

### Examples of Conflicts of Interest

- 1) Financial benefit outside of the evidence synthesis project.
  - a) You are currently employed by, seeking employment from, or have been employed within the last 12 months by an entity which could be perceived to be affected financially from the outcome of this work (excluding VA).
  - b) You have a current grant application (regardless of funding source) that could be perceived to influence your work on this review.
  - c) You have patents, licenses, and/or copyrights, pending or granted, relevant to the work.
- 2) Professional Associations:
  - a) Your work on the review team could be influenced by or appear to be influenced by your service as a Board member, consultant, or other position in a professional association or other entity that has a stake in the results of the review.
- 3) Relationships not covered:
  - a) Please report other relationships which you believe a reasonable person may perceive to influence or give the appearance of influencing your work on this review.

Please check one of the boxes below and provide an explanation of your COI if applicable.

<input checked="" type="checkbox"/>	I have reviewed the topic nomination brief and COI guidance for the above review and am not involved in and have no other conflict of interest regarding the work. I will promptly update this declaration should I discover such a conflict during the review.
<input type="checkbox"/>	I have a conflict of interest in the topic to be reviewed. <i>(Explain below.)</i>

*Conflict of interest being declared:*

**Printed name:** Clarissa Jonas Diamantidis, MD, MHS

**Date:** 09/10/15

**Signature:** Clarissa J.  
Diamantidis

Digitally signed by Clarissa J. Diamantidis  
DN: cn=Clarissa J. Diamantidis, o=Duke University School  
of Medicine, ou=Divisions of General Internal Medicine and  
Nephrology, email=clarissa.diamantidis@duke.edu, c=US  
Date: 2015.09.10 13:42:59 -04'00'

Email this form

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## ICMJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

1. Given Name (First Name) Andrzej      2. Surname (Last Name) Kosinski      3. Date 01-November-2016

4. Are you the corresponding author?     Yes     No      Corresponding Author's Name  
Crowley MJ

5. Manuscript Title  
Clinical outcomes of metformin use in populations with chronic kidney disease, congestive heart failure, or chronic liver disease: a systematic review

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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
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1. Given Name (First Name) Jennifer	2. Surname (Last Name) McDuffie	3. Date 14-November-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Crowley
5. Manuscript Title Clinical Outcomes of Metformin Use in Populations with Chronic Kidney Disease, Congestive Heart Failure, or Chronic Liver Disease: A Systematic Review		
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Jennifer McDuffie 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.

#### 5. Relationships not covered above.

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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) Jennifer	2. Surname (Last Name) McDuffie	3. Date 14-November-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Crowley
5. Manuscript Title Clinical Outcomes of Metformin Use in Populations with Chronic Kidney Disease, Congestive Heart Failure, or Chronic Liver Disease: A Systematic Review		
6. Manuscript Identifying Number (if you know it) M16-1901		

### 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

### 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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Clare Mock 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) Avishek	2. Surname (Last Name) Nagi	3. Date 01-November-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Matt Crowley
5. Manuscript Title Clinical Outcomes of Metformin Use in Populations with Chronic Kidney Disease, Congestive Heart Failure, or Chronic Liver Disease: A Systematic Review		
6. Manuscript Identifying Number (if you know it) M16-1901		

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None

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## ICMJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

1. Given Name (First Name) John	2. Surname (Last Name) Stanifer	3. Date 30-October-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Matthew Crowley
5. Manuscript Title Clinical Outcomes of Metformin Use in Populations with Chronic Kidney Disease, Congestive Heart Failure, or Chronic Liver Disease: A Systematic Review		
6. Manuscript Identifying Number (if you know it)		

### 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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Dr. Stanifer 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) Shuang	2. Surname (Last Name) Tang	3. Date 31-October-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Crowley
5. Manuscript Title Clinical Outcomes of Metformin Use in Populations with Chronic Kidney Disease, Congestive Heart Failure, or Chronic Liver Disease: A Systematic Review		
6. Manuscript Identifying Number (if you know it) M16-1901		

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Are there any relevant conflicts of interest?  Yes  No

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### Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Tang 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) Xianwei	2. Surname (Last Name) Wang	3. Date 01-November-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Crowley
5. Manuscript Title Clinical Outcomes of Metformin Use in Populations with Chronic Kidney Disease, Congestive Heart Failure, or Chronic Liver Disease: A Systematic Review		
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Xianwei Wang has nothing to disclose

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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)  
John

2. Surname (Last Name)  
Williams

3. Date  
31-October-2016

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

5. Manuscript Title  
Clinical Outcomes of Metformin Use in Populations with Chronic Kidney Disease, Congestive Heart Failure, or Chronic Liver Disease: A Systematic Review

6. Manuscript Identifying Number (if you know it)  
M16-1901

### 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
Veterans Administration QUERI	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

### 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?

- 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.

Dr. Williams reports grants from Veterans Administration QUERI, during the conduct of the study; .

### Evaluation and Feedback

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