

## 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.

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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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**Other:** Anything not covered under the previous three boxes

**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)

G Caleb

2. Surname (Last Name)

Alexander

3. Date

09-June-2016

4. Are you the corresponding author?

Yes  No

5. Manuscript Title

BIOEQUIVALENCE OF BIOSIMILAR TUMOR NECROSIS FACTOR-ALPHA (TNF-a) INHIBITORS COMPARED WITH THEIR REFERENCE BIOLOGICS: A SYSTEMATIC REVIEW

6. Manuscript Identifying Number (if you know it)

M16-0428

### 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
Food and Drug Administration	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	This work was supported in part through the FDA-funded Johns Hopkins Center of Excellence in Regulatory Science and Innovation

### 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

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- Yes, the following relationships/conditions/circumstances are present (explain below):
- No other relationships/conditions/circumstances that present a potential conflict of interest

Dr. Alexander is Chair of the FDA's Peripheral and Central Nervous System Advisory Committee; serves as a paid consultant to PainNavigator, a mobile startup to improve patients' pain management; serves as a paid consultant to IMS Health; and serves on an IMS Health scientific advisory board. This arrangement has been reviewed and approved by Johns Hopkins University in accordance with its conflict of interest policies. Dr. Kim has received funding from Pfizer, Lilly, AstraZeneca and Bristol-Myers Squibb through Brigham and Women's Hospital. Dr. Segal and Ms. Chingcuanco have no conflicts of interest to report.

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. Alexander reports contracts from the U.S. Food and Drug Administration (FDA) during the conduct of the study; and Dr. Alexander is Chair of the FDA's Peripheral and Central Nervous System Advisory Committee; serves as a paid consultant to PainNavigator, a mobile startup to improve patients' pain management; serves as a paid consultant to IMS Health; and serves on an IMS Health scientific advisory board. This arrangement has been reviewed and approved by Johns Hopkins University in accordance with its conflict of interest policies. Dr. Kim has received funding from Pfizer, Lilly, AstraZeneca and Bristol-Myers Squibb through Brigham and Women's Hospital. Dr. Segal and Ms. Chingcuanco have no conflicts of interest to report.

### 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) Seoyoung	2. Surname (Last Name) Kim	3. Date 09-June-2016
4. Are you the corresponding author? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Corresponding Author's Name Caleb Alexander
5. Manuscript Title BIOEQUIVALENCE OF BIOSIMILAR TUMOR NECROSIS FACTOR-ALPHA (TNF-a) INHIBITORS COMPARED WITH THEIR REFERENCE BIOLOGICS: A SYSTEMATIC REVIEW		
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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
Pfizer, AstraZeneca, Bristol-Myer Squibb, Lilly, and Genentech	<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. Kim reports grants from Pfizer, AstraZeneca, Bristol-Myer Squibb, Lilly, and Genentech, outside the submitted work; .

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### Section 1. Identifying Information

1. Given Name (First Name)

Jodi

2. Surname (Last Name)

Segal

3. Date

09-June-2016

4. Are you the corresponding author?

 Yes No

Corresponding Author's Name

5. Manuscript Title

BIOEQUIVALENCE OF BIOSIMILAR TUMOR NECROSIS FACTOR-ALPHA (TNF-a) INHIBITORS COMPARED WITH THEIR REFERENCE BIOLOGICS: A SYSTEMATIC REVIEW

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Dr. Segal has nothing to disclose.

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### Section 1. Identifying Information

1. Given Name (First Name)  
Francine

2. Surname (Last Name)  
Chingcuanco

3. Date  
09-June-2016

4. Are you the corresponding author?

Yes  No

Corresponding Author's Name  
G. Caleb Alexander, MD, MS

5. Manuscript Title  
BIOEQUIVALENCE OF BIOSIMILAR TUMOR NECROSIS FACTOR-ALPHA (TNF-a) INHIBITORS COMPARED WITH THEIR REFERENCE BIOLOGICS: A SYSTEMATIC REVIEW

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Ms. Chingcuanco has nothing to disclose.

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