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 in 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.


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 honorary, 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, editing 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

Mamopoulos 1
### Section 1. Identifying Information

1. Given Name (First Name)  
   Apostolos

2. Surname (Last Name)  
   Mamopoulos

3. Date  
   21-March-2016

4. Are you the corresponding author?  
   Yes  
   No  
   Corresponding Author’s Name  
   Guillermina Girardi

5. Manuscript Title  
   Effects of pravastatin in the management of obstetric antiphospholipid syndrome refractory to antithrombotic therapy

6. Manuscript Identifying Number (if you know it)  
   86957-JCI-CMED

### 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.

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

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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.

Generate Disclosure Statement

Dr. Mamopoulos has nothing to disclose.
# ICMJE Form for Disclosure of Potential Conflicts of Interest

## Section 1. Identifying Information

1. Given Name (First Name)  
   Christos

2. Surname (Last Name)  
   Vosnakis

3. Date  
   21-March-2016

4. Are you the corresponding author?  
   Yes ✅ No

   Corresponding Author’s Name  
   Guillermina Girardi

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Generate Disclosure Statement

Dr. Vosnakis has nothing to disclose.
ICMJE Form for Disclosure of Potential Conflicts of Interest

**Section 1. Identifying Information**

1. Given Name (First Name) | David
2. Surname (Last Name) | Rousso
3. Date | 22-March-2016
4. Are you the corresponding author? | Yes ✔ No
   Corresponding Author’s Name | Guillermina Girardi
5. Manuscript Title
   Effects of pravastatin in the management of obstetric antiphospholipid syndrome refractory to antithrombotic therapy
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Are there any relevant conflicts of interest? | Yes ✔ No

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Generate Disclosure Statement

Dr. Rousso has nothing to disclose.
ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)          2. Surname (Last Name)          3. Date
Eleftheria                            Lefkou                        21-March-2016

4. Are you the corresponding author?  Yes  No

Corresponding Author’s Name
Guillemina Gitardi

5. Manuscript Title
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86957-JCICMED

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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

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**Generate Disclosure Statement**

Dr. Lefkou has nothing to disclose.
ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)  Guillermína
2. Surname (Last Name)  Girardi
3. Date  20-March-2016
4. Are you the corresponding author?  ✔ Yes  ❑ No

5. Manuscript Title
Effects of pravastatin in the management of obstetric antiphospholipid syndrome refractory to antithrombotic therapy

6. Manuscript Identifying Number (if you know it)
B6957-IC-CMED

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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

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Generate Disclosure Statement

Dr. Girardi has nothing to disclose.
ICMJE Form for Disclosure of Potential Conflicts of Interest

### Section 1. Identifying Information

1. Given Name (First Name)  
   Themistoklis
2. Surname (Last Name)  
   Dagklis
3. Date  
   21-March-2016
4. Are you the corresponding author?  
   Yes  
   No  
   Corresponding Author’s Name
   Guillermina Girardi
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Are there any relevant conflicts of interest?  
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Generate Disclosure Statement

Dr. Dagklis has nothing to disclose.
### STROBE Statement—Checklist of items that should be included in reports of *case-control studies*

<table>
<thead>
<tr>
<th>Item No</th>
<th>Recommendation</th>
</tr>
</thead>
</table>
| **Title and abstract** | 1 (a) Indicate the study’s design with a commonly used term in the title or the abstract  
(b) Provide in the abstract an informative and balanced summary of what was done and what was found |
| **Introduction** | 2 Explain the scientific background and rationale for the investigation being reported |
| **Objectives** | 3 State specific objectives, including any prespecified hypotheses |
| **Methods** | 4 Present key elements of study design early in the paper |
| **Setting** | 5 Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection |
| **Participants** | 6 (a) Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls  
(b) For matched studies, give matching criteria and the number of controls per case |
| **Variables** | 7 Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable |
| **Data sources/measurement** | 8* For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group |
| **Bias** | 9 Describe any efforts to address potential sources of bias |
| **Study size** | 10 Explain how the study size was arrived at |
| **Quantitative variables** | 11 Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why |
| **Statistical methods** | 12 (a) Describe all statistical methods, including those used to control for confounding  
(b) Describe any methods used to examine subgroups and interactions  
(c) Explain how missing data were addressed  
(d) If applicable, explain how matching of cases and controls was addressed  
(e) Describe any sensitivity analyses |
| **Results** | 13* (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed  
(b) Give reasons for non-participation at each stage  
(c) Consider use of a flow diagram |
| **Descriptive data** | 14* (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders  
(b) Indicate number of participants with missing data for each variable of interest |
| **Outcome data** | 15* Report numbers in each exposure category, or summary measures of exposure |
| **Main results** | 16 (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included  
(b) Report category boundaries when continuous variables were categorized  
(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period |
### Other analyses

17. Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses

### Discussion

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key results</td>
<td>18</td>
<td>Summarise key results with reference to study objectives</td>
</tr>
<tr>
<td>Limitations</td>
<td>19</td>
<td>Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias</td>
</tr>
<tr>
<td>Interpretation</td>
<td>20</td>
<td>Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence</td>
</tr>
<tr>
<td>Generalisability</td>
<td>21</td>
<td>Discuss the generalisability (external validity) of the study results</td>
</tr>
</tbody>
</table>

### Other information

<table>
<thead>
<tr>
<th>Category</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Funding</td>
<td>22</td>
<td>Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based</td>
</tr>
</tbody>
</table>

*Give information separately for cases and controls.*