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)  
   Annemieke

2. Surname (Last Name)  
   Boot

3. Date  
   09-February-2018

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

   Corresponding Author’s Name  
   Thomas Carpenter

5. Manuscript Title  
   Burosumab Therapy for Children with X-linked Hypophosphatemic Rickets

6. Manuscript Identifying Number (if you know it)  
   17-1461.R1

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.

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<td>Ultragenyx</td>
<td>☑</td>
<td>☑</td>
<td></td>
<td></td>
<td>Research funds for the study, consulting fee</td>
</tr>
</tbody>
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Are there any relevant conflicts of interest?  
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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. Boot reports grants and personal fees from Ultragenyx, 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)  
   Thomas

2. Surname (Last Name)  
   Carpenter

3. Date  
   06-February-2018

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

5. Manuscript Title  
   Burosumab Therapy for Children with X-linked Hypophosphatemia

6. Manuscript Identifying Number (if you know it)  
   17-14641

Section 2. The Work Under Consideration for Publication

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

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<tr>
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</table>

Yale University performed much of the work under contract to the sponsor, Ultragenyx. The PI was paid consulting fees for assistance in the design of the studies prior to the initiation of the contract for performing the study. Writing assistance was provided in the preparation of the manuscript by the sponsor.

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<td>I served as consultant and chair of DSMB for the trials related to use of asfotase alfa, developed for the use of another, separate metabolic bone disease in children.</td>
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<tr>
<td>Clementia</td>
<td></td>
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<td></td>
<td>I serve as a consultant for trials related to the development of a therapy for another bone disease.</td>
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<td>Inozyme</td>
<td></td>
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<td></td>
<td>I serve as a consultant for development of the use of an enzyme with therapeutic potential in other rare disorders of calcification.</td>
</tr>
</tbody>
</table>

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

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

- Yes  
- No  

- ✔ No

**Section 5. Relationships not covered above**

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Section 1. Identifying Information

1. Given Name (First Name)  
Chao-Yin

2. Surname (Last Name)  
Chen

3. Date  
15-February-2018

4. Are you the corresponding author?  
Yes  
No  
✔

Corresponding Author’s Name  
Thomas Carpenter

5. Manuscript Title  
Burosumab Therapy for Children with X-Linked Hypophosphatemia

6. Manuscript Identifying Number (if you know it)  
17-14641

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Are there any relevant conflicts of interest?  
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No  
✔

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<tr>
<td>Ultragenyx Pharmaceutical Inc.</td>
<td></td>
<td>✔</td>
<td></td>
<td>✔</td>
<td>Employee and Shareholder</td>
</tr>
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Section 1. Identifying Information

1. Given Name (First Name)  Wolfgang
2. Surname (Last Name)  Högler
3. Date  08-February-2018
4. Are you the corresponding author?  Yes  ✔  No
5. Manuscript Title  Burosumab Therapy for Children with X-linked Hypophosphatemia
6. Manuscript Identifying Number (if you know it)  17-14641

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<td>✔</td>
<td></td>
<td>Consulting; Travel reimbursements, for presentation of data at scientific conferences</td>
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| Dr. Högler reports personal fees and non-financial support from Ultragenyx Pharmaceutical Inc., outside the submitted work. |

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**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)  
   Erik

2. Surname (Last Name)  
   Imel

3. Date  
   06-February-2018

4. Are you the corresponding author?  
   ✔ Yes  
   No

5. Manuscript Title  
   Burosumab Therapy for Children with X-linked Hypophosphatemia

6. Manuscript Identifying Number (if you know it)  
   17-14641

### 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.

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Ultragenyx Pharmaceutical Inc.</td>
<td>✔</td>
<td>No</td>
<td>No</td>
<td>✔</td>
<td>clinical trials grants</td>
</tr>
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</table>

### 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

If yes, please fill out the appropriate information below.

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</table>
Section 4. Intellectual Property -- Patents & Copyrights

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

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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Dr. Imel reports grants from Ultragenyx Pharmaceutical Inc., during the conduct of the study; grants and other from Ultragenyx Pharmaceutical Inc., outside the submitted work.

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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)  Emil
2. Surname (Last Name)  Kakkis
3. Date  06-February-2018
4. Are you the corresponding author?  ✔ Yes  ❌ No
   Corresponding Author’s Name  Thomas O. Carpenter
5. Manuscript Title
   Burosumab Therapy for Children with X-linked Hypophosphatemia
6. Manuscript Identifying Number (if you know it)
   17-14641

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
If yes, please fill out the appropriate information below.

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<tr>
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<td>✔</td>
<td></td>
<td>✔</td>
<td>Employee (CEO and Founder) and shareholder</td>
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</table>

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.
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<td>U.S. Application Serial No. 14/725,320</td>
<td>✔</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>I am a co-inventor of the referenced patent application. The patent application is jointly owned by Ultragenyx Pharmaceutical Inc., the company which sponsored the clinical trial UX023-CL201.</td>
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<tr>
<td>U.S. Patent No. 7,883,705</td>
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<td></td>
<td>✔</td>
<td></td>
<td>Ultragenyx Pharmaceutical Inc. has licensed this patent related to the burosumab antibody. Ultragenyx Pharmaceutical Inc. is the company which sponsored the clinical trial UX023-CL201.</td>
</tr>
<tr>
<td>U.S. Patent No. 9,290,569</td>
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<td>✔</td>
<td></td>
<td></td>
<td>Ultragenyx Pharmaceutical Inc. has licensed this patent related to the burosumab antibody. Ultragenyx Pharmaceutical Inc. is the company which sponsored the clinical trial UX023-CL201.</td>
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<tr>
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<td>✔</td>
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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):

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ICMJE Form for Disclosure of Potential Conflicts of Interest

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. Kakkis reports personal fees and other from Ultragenyx Pharmaceutical Inc., outside the submitted work; in addition, Dr. Kakkis has a patent U.S. Application Serial No. 14/725,320 pending, a patent U.S. Patent No. 7,883,705 licensed to Ultragenyx Pharmaceutical, Inc., a patent U.S. Patent No. 9,290,569 licensed to Ultragenyx Pharmaceutical, Inc., and a patent U.S. Application Serial No. 15/040,103 licensed to Ultragenyx Pharmaceutical, Inc.

Evaluation and Feedback

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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) Agnès
2. Surname (Last Name) Linglart
3. Date 21-February-2018
4. Are you the corresponding author? Yes ✔ No
   Corresponding Author’s Name Thomas Carpenter
5. Manuscript Title Burosumab Therapy for Children with X-linked Hypophosphatemia
6. Manuscript Identifying Number (if you know it) 17-14641

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.

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<td>Ultragenyx</td>
<td>✔</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
<td>The hospital received payment for conducting the study and support for the investigators</td>
</tr>
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Dr. Linglart reports grants from Ultragenyx 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)  Meng
2. Surname (Last Name)  Mao
3. Date  12-February-2018
4. Are you the corresponding author?  No
5. Manuscript Title
   Burosumab Therapy for Children with X-Linked Hypophosphatemia
6. Manuscript Identifying Number (if you know it)
   17-14641

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Are there any relevant conflicts of interest?  No

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<td></td>
<td>✔</td>
<td></td>
<td>✔</td>
<td>Employee and Shareholder</td>
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Dr. Mao reports personal fees and other from Ultragenyx Pharmaceutical Inc., outside the submitted work.

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

Padidela
**Section 1. Identifying Information**

1. **Given Name (First Name)**
   - Raja

2. **Surname (Last Name)**
   - Padidela

3. **Date**
   - 09-February-2018

4. **Are you the corresponding author?**
   - Yes ✔

5. **Manuscript Title**
   - Burosumab Therapy for Children with X-linked Hypophosphatemia

6. **Manuscript Identifying Number (if you know it)**
   - 17-14641

**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.

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<td></td>
<td></td>
<td>Chief investigator on clinical trial and member of scientific advisory boards</td>
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<tr>
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<td></td>
<td></td>
<td>Personal fee for educational activities and scientific advisory boards</td>
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**Section 3. Relevant financial activities outside the submitted work.**

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Are there any relevant conflicts of interest?  ✔ Yes  ✔ No  

If yes, please fill out the appropriate information below.

<table>
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<tr>
<th>Name of Entity</th>
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</table>
Section 4. Intellectual Property -- Patents & Copyrights

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

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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Dr. Padidela reports grants and personal fees from Ultragenyx, personal fees from Kyowa Kirin Ltd - Kyowa Kirin International, during the conduct of the study; personal fees from Novo Nordisk, personal fees from Alexion, outside the submitted work; .

Evaluation and Feedback

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**ICMJE Form for Disclosure of Potential Conflicts of Interest**

### Section 1. Identifying Information

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<tr>
<td>Anthony</td>
<td>Portale</td>
<td>13-February-2018</td>
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4. Are you the corresponding author?  
   ✔ Yes  
   No

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<th>4. Are you the corresponding author?</th>
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</tr>
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<tr>
<td>Yes</td>
<td>Thomas Carpenter</td>
</tr>
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</table>

5. Manuscript Title  
   Burosumab Therapy for Children with X-linked Hypophosphatemia

6. Manuscript Identifying Number (if you know it)  
   17-14641

### 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.

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   ✔ No

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Do you have any patents, whether planned, pending or issued, broadly relevant to the work?  
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   ✔ No
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Dr. Portale reports grants, personal fees and non-financial support from Ultragenyx Pharmaceuticals, 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) 
   Javier

2. Surname (Last Name) 
   San Martin

3. Date 
   12-February-2018

4. Are you the corresponding author? 
   Yes ☐ No ☑
   Corresponding Author’s Name
   Thomas Carpenter

5. Manuscript Title
   Burosumab Therapy for Children with X-Linked Hypophosphatemia

6. Manuscript Identifying Number (if you know it)
   17-14641

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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 ☐

If yes, please fill out the appropriate information below.

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<td>Ultragenyx Pharmaceutical Inc.</td>
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<td>Employee and Shareholder</td>
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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.
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I am a co-inventor of the referenced patent application. The patent application is jointly owned by Ultragenyx Pharmaceutical Inc., the company which sponsored the clinical trial UX023-CL201.

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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Dr. San Martin reports personal fees and other from Ultragenyx Pharmaceutical Inc., outside the submitted work; In addition, Dr. San Martin has a patent U.S. Application Serial No. 14/725,320 pending.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)  
   Alison

2. Surname (Last Name)  
   Skrinar

3. Date  
   12-February-2018

4. Are you the corresponding author?  
   ✔ No

   Corresponding Author’s Name  
   Thomas Carpenter

5. Manuscript Title  
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# ICMJE Form for Disclosure of Potential Conflicts of Interest

**Section 1.** Identifying Information

1. Given Name (First Name)  
   William

2. Surname (Last Name)  
   van’t Hoff

3. Date  
   07-February-2018

4. Are you the corresponding author?  
   Yes ✔ No

   Corresponding Author’s Name  
   Thomas Carpenter

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<td>✔</td>
<td>Travel/accommodation for 2 Investigator meetings, fee for Advisory Board to Institution</td>
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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.
   - 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) Michael
2. Surname (Last Name) Whyte
3. Date 06-February-2018
4. Are you the corresponding author? Yes ✔ No
Corresponding Author’s Name
Thomas Carpenter
5. Manuscript Title
Burosumab Therapy for Children with X-linked Hypophosphatemia
6. Manuscript Identifying Number (if you know it)
17-14641

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.

<table>
<thead>
<tr>
<th></th>
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<tbody>
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<td>Ultragenyx Pharmaceutical Inc.</td>
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<td>✔</td>
<td></td>
<td></td>
<td>Consulting</td>
</tr>
</tbody>
</table>

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

If yes, please fill out the appropriate information below.

<table>
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<tr>
<th>Name of Entity</th>
<th>Grant?</th>
<th>Personal Fees?</th>
<th>Non-Financial Support?</th>
<th>Other?</th>
<th>Comments</th>
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</tr>
</tbody>
</table>
Section 4. Intellectual Property -- Patents & Copyrights

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

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. Whyte reports grants and personal fees from Ultragenyx Pharmaceutical Inc. during the conduct of the study; grants and other from Merck, Inc., grants from Alexion, outside the submitted work.

Evaluation and Feedback

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