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”.

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This section asks about patents and copyrights, whether pending, issued, licensed and/or receiving royalties.

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Royalties: Funds are coming into 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)  Seema
2. Surname (Last Name)   Bhatt
3. Date  13-April-2018
4. Are you the corresponding author?  ☐ Yes  ☑ No
   Corresponding Author’s Name  David Schnadower
5. Manuscript Title
   Lactobacillus rhamnosus GG vs. Placebo for Pediatric Acute Gastroenteritis
6. Manuscript Identifying Number (if you know it)
   18-02598

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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Section 6. Disclosure Statement

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Dr. Bhatt 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)  
Theron

2. Surname (Last Name)  
Casper

3. Date  
12-April-2018

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

5. Manuscript Title  
Lactobacillus rhamnosus GG vs. Placebo for Pediatric Acute Gastroenteritis

6. Manuscript Identifying Number (if you know it)  
18-02598

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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Dr. Casper reports grants from Health Resources and Services Administration and NIH/National Institute of Child Health and Human Development, during the conduct of the study.

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Section 1. Identifying Information

1. Given Name (First Name)  
   J. Michael

2. Surname (Last Name)  
   Dean

3. Date  
   17-April-2018

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

   Corresponding Author’s Name  
   David Schnucedow

5. Manuscript Title  
   Lactobacillus rhamnosus GG vs. Placebo for Pediatric Acute Gastroenteritis

6. Manuscript Identifying Number (if you know it)  
   18-02598

Section 2. The Work Under Consideration for Publication

Did you or your institution at any time

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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Dr. Dean reports grants from National Institute of Child Health and Human Development during the conduct of the study.

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**Section 1. Identifying Information**

1. Given Name (First Name)  
Viani

2. Surname (Last Name)  
Dickey

3. Date  
18-April-2018

4. Are you the corresponding author?  
☐ Yes  ✔ No  
Corresponding Author’s Name  
David Schnadower

5. Manuscript Title  
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6. Manuscript Identifying Number (if you know it)  
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Dr. Dickey has nothing to disclose.

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Section 1. Identifying Information

1. Given Name (First Name)  
   Stephen

2. Surname (Last Name)  
   Freedman

3. Date  
   04-September-2018

4. Are you the corresponding author?  
   Yes  No

   Corresponding Author’s Name  
   David Schnadower

5. Manuscript Title  
   Lactobacillus rhamnosus GG vs. Placebo for Pediatric Acute Gastroenteritis

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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.

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<td>Professorship in Child Health and Wellness</td>
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Do you have any patents, whether planned, pending or issued, broadly relevant to the work?  Yes  No
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☐ Yes, the following relationships/conditions/circumstances are present (explain below):
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Having received study drug (probiotic) and placebo for the conduct of a separate comparative effectiveness RCT from Lallemand Health Solutions Inc.

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Dr. Freedman reports grants from Alberta Children’s Hospital Foundation outside the submitted work. Dr. Freedman received study drug (probiotic) and placebo for the conduct of a separate comparative effectiveness RCT from Lallemand Health Solutions Inc.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)  
Marc

2. Surname (Last Name)  
Gorelick

3. Date  
12-April-2018

4. Are you the corresponding author?  
[ ] Yes  [ ] No

Corresponding Author’s Name  
David Schnadower

5. Manuscript Title  
Lactobacillus rhamnosus GG vs. Placebo for Pediatric Acute Gastroenteritis

6. Manuscript Identifying Number (if you know it)  
18-02598

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Are there any relevant conflicts of interest?  
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Dr. Gorelick 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)  
Carl
2. Surname (Last Name)  
Hall-Moore
3. Date  
13-April-2018

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

5. Manuscript Title  
Lactobacillus rhamnosus GG vs. Placebo for Pediatric Acute Gastroenteritis

6. Manuscript Identifying Number (if you know it)  
18-02598

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Dr. Hall-Moore 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)  
Adam

2. Surname (Last Name)  
Levine

3. Date  
12-April-2018

4. Are you the corresponding author?  
[ ] Yes  [✓] No

Corresponding Author’s Name  
David Schnadower

5. Manuscript Title  
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6. Manuscript Identifying Number (if you know it)  
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Dr. Levine reports grants from National Institutes of Health during the conduct of the study.

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Section 1. Identifying Information

1. Given Name (First Name)  
Prashant

2. Surname (Last Name)  
Mahajan

3. Date  
12-April-2018

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

5. Manuscript Title  
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6. Manuscript Identifying Number (if you know it)  
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Dr. Mahajan reports grants from National Institute of Child Health and Human Development during the conduct of the study.

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Section 1. Identifying Information

1. Given Name (First Name)  
   Melissa

2. Surname (Last Name)  
   Metheney

3. Date  
   13-April-2018

4. Are you the corresponding author?  
   Yes  
   No

   Corresponding Author's Name  
   David Schnadower

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)**
   - Karen

2. **Surname (Last Name)**
   - O’Connell

3. **Date**
   - 15-April-2018

4. **Are you the corresponding author?**
   - [ ] Yes  ✔ No

   **Corresponding Author’s Name**
   - David Schnadower

5. **Manuscript Title**
   - Lactobacillus rhamnosus GG vs. Placebo for Pediatric Acute Gastroenteritis

6. **Manuscript Identifying Number (if you know it)**
   - 18-02598

### 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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- [ ] 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. O’Connell 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) Cody
2. Surname (Last Name) Olsen
3. Date 12-April-2018

4. Are you the corresponding author? Yes No

Corresponding Author's Name David Schandower

5. Manuscript Title
Lactobacillus rhamnosus GG vs. Placebo for Pediatric Acute Gastroenteritis

6. Manuscript Identifying Number (if you know it)
18-02598

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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Section 6. Disclosure Statement

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Mr. Olsen has nothing to disclose.

Evaluation and Feedback

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

Powell
ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)  
   Elizabeth

2. Surname (Last Name)  
   Powell

3. Date  
   12-April-2018

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

   Corresponding Author’s Name
   David Schnadower

5. Manuscript Title
   Lactobacillus rhamnosus GG vs. Placebo for Pediatric Acute Gastroenteritis

6. Manuscript Identifying Number (if you know it)
   18-02598

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>National Institute of Child Health and Human Development</td>
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<td>☐</td>
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<td>☐</td>
<td>Subcontract from Dr. Schnadower’s RO1 grant</td>
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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.

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<th>Name of Entity</th>
<th>Grant?</th>
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<th>Non-Financial Support?</th>
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Dr. Powell reports grants from National Institute of Child Health and Human Development during the conduct of the study, as well as grants from Children’s National Medical Center, Hasbro Children’s Hospital, and Wayne State University outside the submitted work.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)  
   Alexander

2. Surname (Last Name)  
   Rogers

3. Date  
   12-April-2018

4. Are you the corresponding author?  
   Yes ☑ No

Corresponding Author's Name
   David Schnadower

5. Manuscript Title  
   Lactobacillus rhamnosus GG vs. Placebo for Pediatric Acute Gastroenteritis

6. Manuscript Identifying Number (if you know it)  
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Roskind
ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)  
Cindy

2. Surname (Last Name)  
Roskind

3. Date  
15-April-2018

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

Corresponding Author’s Name  
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Dr. Roskind has nothing to disclose.

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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.

1. Identifying information.

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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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**LTI:** 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)  
   Robert

2. Surname (Last Name)  
   Sapien

3. Date  
   12-September-2018

4. Are you the corresponding author?  
   Yes  No
   Corresponding Author’s Name  
   David Schnadower

5. Manuscript Title  
   Lactobacillus rhamnosus GG vs. Placebo for Pediatric Acute Gastroenteritis

6. Manuscript Identifying Number (if you know it)  
   18-02598

**Section 2. The Work Under Consideration for Publication**

Did you or your institution at any time

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>
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</tr>
</thead>
<tbody>
<tr>
<td>National Institute of Child Health and Human Development</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
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1. Given Name (First Name)  
David
2. Surname (Last Name)  
Schnadower
3. Date  
12-September-2018
4. Are you the corresponding author?  
✓ Yes   ☐ No
5. Manuscript Title  
Lactobacillus rhamnosus GG vs. Placebo for Pediatric Acute Gastroenteritis
6. Manuscript Identifying Number (if you know it)  
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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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<thead>
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</thead>
<tbody>
<tr>
<td>National Institute of Child Health and Human Development</td>
<td>✓</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>RO1 Grant</td>
</tr>
<tr>
<td>iHealth Inc.</td>
<td>☐</td>
<td>☐</td>
<td>✓</td>
<td>☐</td>
<td>Lactobacillus Rhamnosus GG and placebo capsules were provided in kind by iHealth Inc. for the study. iHealth Inc. personnel had no role in study design, data management, analysis and interpretation of data; nor did they have any role or authority in writing the report nor the decision to submit the trial for publication</td>
</tr>
</tbody>
</table>

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<tr>
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<th>Personal Fees?</th>
<th>Non-Financial Support?</th>
<th>Other?</th>
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<td>National Institutes of Health</td>
<td>☑</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>co-investigator</td>
</tr>
<tr>
<td>Health Resources and Services Administration</td>
<td>☑</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>co-investigator</td>
</tr>
<tr>
<td>Cincinnati Children’s Hospital Medical Center</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☑</td>
<td>Richard and Barbara Ruddy Endowed Chair in Emergency Medicine</td>
</tr>
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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. Schnadower reports grants from National Institute of Child Health and Human Development and non-financial support from iHealth Inc. during the conduct of the study, as well as grants from National Institutes of Health and Health Resources and Services Administration and other support from Cincinnati Children’s Hospital Medical Center outside the submitted work.
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### Section 1. Identifying Information

1. Given Name (First Name)  
   Phillip  

2. Surname (Last Name)  
   Tarr  

3. Date  
   17-April-2018  

4. Are you the corresponding author?  
   [ ] Yes  
   [x] No  

   Corresponding Author’s Name  
   David Schnadower

5. Manuscript Title  
   Lactobacillus rhamnosus GG vs. Placebo for Pediatric Acute Gastroenteritis

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   [ ] No

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<th>Non-Financial Support</th>
<th>Other</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Institute of Child Health and Human Development</td>
<td>[x]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>Co-investigator on Dr. Schnadower’s grant</td>
</tr>
</tbody>
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<th>Non-Financial Support?</th>
<th>Other?</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>MediBeacon Inc</td>
<td></td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>Consultant, Equity, Member of Scientific Advisory Board, and co-inventor on a US patent (application number 14/538770, Compositions and Methods For Assessing Gut Function) that might generate royalty payments. The patent is assigned to MediBeacon Inc, and has not been granted or licensed to any other parties. Royalties have not been generated.</td>
</tr>
<tr>
<td>Bill &amp; Melinda Gates Foundation</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>Investigator on projects related to childhood gut health and disease Consult on a project studying infections in infants in low and middle income countries. (P30DK052574)</td>
</tr>
<tr>
<td>Washington University Digestive Diseases Research Core Center</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>One-time consultant on the microbiome.</td>
</tr>
<tr>
<td>Bio-Rad</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
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Cheryl

2. Surname (Last Name)  
Vance

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Dr. Vance has nothing to disclose.

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