

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 has five parts.

1. Identifying information.

Each author should submit a separate form. Provide complete information and double-check the manuscript number. If you are NOT the corresponding author please insert his or her name.

2. The work under consideration for publication.

Please provide 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 idea is to provide for the reader information about resources that you received, either directly or indirectly (via your institution), to enable you to complete the work. If you check the "No" box it 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 to pay you. If you or your institution did receive funds from a third party to support the work, check "Yes" along with the appropriate boxes to indicate the type of support and whether you or your institution received it.

3. Relevant financial activities outside the submitted work.

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5. Nonfinancial associations.

Please report any personal, professional, political, institutional, religious, or other associations that a reasonable reader would want to know about in relation to the submitted work.



| | • | | | | | |
|------------------------|---|-----------------------|--------------------|-------------------|---------------------|-----------------------|
| Given Name: (or first) | Kenneth | Surname: (or last) | Schulz | | Effective Date: | 30-November-2009 |
| Are you th | e corresponding author? | ĭ Yes □ N | lo Io | | Format exam | ple: 07-August-2008 |
| Manuscript T | itle: CONSORT 2010 State | ement: Updated | d Guidelines for I | Reporting Paralle | l-Group Randomized | Trials |
| Manuscript Io | dentifying Number (if y | ou know it): [| | | | |
| Section 2. Inf | ormation about the | support of tl | he work und | er considerat | ion for publication | on. |
| • | r institution at any time res, data monitoring board, | 1 , | T T | , , | | ork (including but no |
| ☐ No | | | | | | |
| ⊠ Yes, sp | ecify nature of compensat | tion | | | | |

If you have more than one relationship, click "Add +" to add a row. Click "Del ×" to delete an extra row.

Section 1. Identifying Information.

| Туре | Money Paid to You* | | Money to Your Institution | | Name of Entity | Comments** | |
|---|-----------------------|-----|---------------------------------|-----|--|------------|-------|
| | No | Yes | No | Yes | | | |
| Grant | | | | | | | Del × |
| | ' | | • | | - | | Add + |
| Consulting fee or honorarium | \boxtimes | | | | | | Del × |
| | | | • | • | | | Add + |
| Support for travel to meetings for the study or otherwise | | | | | Presidents Fund | | Del × |
| Support for travel to meetings for the study or otherwise | | | | | Johnson & Johnson | | Del × |
| Support for travel to meetings for the study or otherwise | | | | | British Medical Journal | | Del × |
| Support for travel to meetings for the study or otherwise | | | | | American Society for Clinical Oncology | | Del × |
| | ı | | 1 | 1 | 1 | | Add + |



| Туре | | y Paid ′ou* | Yo | ey to our oution | Name of Entity | Comments** | |
|--|-------------|----------------|-------------|------------------------|----------------|------------|-------|
| Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like | \boxtimes | | | | | | Del × |
| | | | | | | | Add + |
| Payment for writing or reviewing the manuscript | | | \boxtimes | | | | Del × |
| | • | | | | | | Add + |
| Support in kind such as writing, provision of medicines or equipment, or administrative support | \boxtimes | | | | | | Del × |
| | | | | | | | Add + |
| Other | \boxtimes | | \boxtimes | | | | Del× |
| | | | | | | | Add + |

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| Type of Relationship (in alphabetical order) | No | Money Paid to You | Money to Your institution | Entity | Comments | |
|--|-------------|-------------------------|---------------------------------|--------|----------|-------|
| Board membership | \boxtimes | | | | | Del × |
| | | | | | | Add + |
| Consultancy | | | | Wyeth | | Del × |
| | | | | | | Add + |
| Employment | \boxtimes | | | | | Del × |

^{**}Use this section to provide any needed explanation



| Type of Relationship (in alphabetical order) | No | Money Paid to You | Money to Your institution | Entity | Comments | |
|---|-------------|-------------------------|---------------------------------|---|----------|-------|
| | | | | | | Add + |
| Expert testimony | \boxtimes | | | | | Del × |
| | | | • | | | Add + |
| Gifts | \boxtimes | | | | | Del× |
| | | | | | | Add + |
| Grants/grants pending | \boxtimes | | | | | Del × |
| | | I | T | American Board of | | Add + |
| Honoraria | | | | Obstetrics and Gynecology Foundation for Exxcellence in Women's Health Care | | Del × |
| Honoraria | | \boxtimes | | Ortho-McNeil Janssen Scientific Affairs | | Del × |
| Honoraria | | \boxtimes | | American College of Obstetrics and Gynecology | | Del × |
| | | | I | , 3, | | Add + |
| Payment for manuscript preparation | \boxtimes | | | | | Del × |
| | | <u> </u> | | | | Add + |
| Patents (planned, pending or issued) | | | | | | Del × |
| | | | | T I | | Add + |
| Royalties | \boxtimes | | | | | Del × |
| | | | | | | Add + |
| Payment for development of educational presentations including service on speakers' bureaus | | | | | | Del × |
| | | | • | | | Add + |
| Stock/stock options | \boxtimes | | | | | Del × |
| | | | | | | Add + |
| Travel/accommodations expenses covered or reimbursed | | | | EQUATOR Network | | Del × |
| | | | | | | Add + |



| Type of Relationship (in alphabetical order) | No | Money Paid to You | Money to Your institution | Entity | Comments | |
|--|-------------|-------------------------|---------------------------------|--------|----------|-------|
| Other (err on the side of full disclosure) | \boxtimes | | | | | Del × |
| | | | | | | Add + |

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| Do your children or your spouse or partner l | nave financial relationships wit | th entities that have an interest in the | he content of the |
|--|----------------------------------|--|-------------------|
| submitted work? | | | |

| \times | No other relationships/conditions/circumstances that present pote | ential conflict of interest |
|----------|--|-----------------------------|
| | Yes, the following relationships/conditions/circumstances are pres | sent (explain below): |

Section 5. Information about relevant nonfinancial associations.

| Do you have any relevant nonf | inancial associations | or interests | (personal, | professional, | political, | institutional, | religious, | or other) |
|--------------------------------|-----------------------|----------------|------------|---------------|------------|----------------|------------|-----------|
| that a reasonable reader would | want to know about | in relation to | the subn | nitted work? | | | | |

| \boxtimes | No relevant nonfinancial relationships/conditions/circumstances to report. | | |
|-------------|---|-------------|------|
| П | Yes, the following relevant nonfinancial relationships/conditions/circumstances are present (| explain bel | ow): |

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Given Name: Surname: Effective Date: 19-December-2009 Douglas Altman (or first) (or last) Format example: 07-August-2008 Are you the corresponding author? \(\subseteq\) Yes \(\subseteq\) No Corresponding author's name: Kenneth Schulz Manuscript Title: | CONSORT 2010 Statement Manuscript Identifying Number (if you know it): M10-0379 Section 2. Information about the support of the work under consideration for publication. Did you or your institution at any time receive payment or support in kind for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc...)? ☐ No X Yes, specify nature of compensation

If you have more than one relationship, click "Add +" to add a row. Click "Del ×" to delete an extra row.

Section 1. Identifying Information.

| Туре | Money Paid to You* | | Money to Your Institution | | Name of Entity | Comments** | |
|---|-----------------------|-----|---------------------------------|-------------|--|------------|-------|
| | No | Yes | No | Yes | | | |
| Grant | | | | \boxtimes | NIHR/MRC | | Del × |
| | - | • | | • | | | Add + |
| Consulting fee or honorarium | | | | | | | Del × |
| | | | • | • | | | Add + |
| Support for travel to meetings for the study or otherwise | | | | | Presidents Fund | | Del × |
| Support for travel to meetings for the study or otherwise | | | | | Johnson & Johnson | | Del × |
| Support for travel to meetings for the study or otherwise | | | | | British Medical Journal | | Del × |
| Support for travel to meetings for the study or otherwise | | | | | American Society for Clinical Oncology | | Del × |



| Туре | | y Paid ′ou* | Yo | ey to our oution | Name of Entity | Comments** | |
|--|-------------|----------------|-------------|------------------------|----------------|------------|-------|
| | | | | | | | Add + |
| Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like | | | \boxtimes | | | | Del × |
| | | | | | | | Add + |
| Payment for writing or reviewing the manuscript | \boxtimes | | \boxtimes | | | | Del × |
| | | | | | | | Add + |
| Support in kind such as writing, provision of medicines or equipment, or administrative support | | | | | | | Del × |
| | | | | · ' | | | Add + |
| Other | \boxtimes | | \boxtimes | | | | Del × |
| | | | | | | | Add + |

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|--|-------------|-------------------------|---------------------------------|--------|----------|-------|
| Board membership | \boxtimes | | | | | Del × |
| | | | | | | Add + |
| Consultancy | \boxtimes | | | | | Del× |
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|---|-------------|-------------------------|---------------------------------|-----------------|----------|-------|
| Employment | \boxtimes | | | | | Del× |
| | | | | | | Add + |
| Expert testimony | \boxtimes | | | | | Del × |
| | | | | | | Add + |
| Gifts | \boxtimes | | | | | Del× |
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| Grants/grants pending | \boxtimes | | | | | Del × |
| | | _ | | | I | Add + |
| Honoraria | | | | | | Del× |
| Payment for manuscript | | | | | | Add + |
| preparation | | | | | | Del × |
| | | | | T | I | Add + |
| Patents (planned, pending or issued) | | | | | | Del × |
| | | | 1 | 1 | 1 | Add + |
| Royalties | \boxtimes | | | | | Del× |
| | | | | | | Add + |
| Payment for development of educational presentations including service on speakers' bureaus | \boxtimes | | | | | Del × |
| | | | | | | Add + |
| Stock/stock options | \boxtimes | | | | | Del× |
| | | | | | | Add + |
| Travel/accommodations expenses covered or reimbursed | | | | EQUATOR Network | | Del × |
| | | | | | | Add + |
| Other (err on the side of full disclosure) | \boxtimes | | | | | Del × |
| | | | | | | Add + |



Section 4. Information about financial relationships involving your spouse or partner or your children (under 18 years of age).

| Do your children or your spouse or partner have financial relationships with entities that have an interest in the content of the submitted work? |
|---|
| No other relationships/conditions/circumstances that present potential conflict of interest |
| Yes, the following relationships/conditions/circumstances are present (explain below): |
| |

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|---|
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| Section 1. Ide | entifying Information | l . | | | | | |
|------------------------|---|--------------------|--------------------|--------------------|--------------------|-----------------------|--|
| Given Name: (or first) | David | Surname: (or last) | lMoher | | Effective Date: | 28-November-2009 | |
| Are you the | e corresponding author? | Yes 1 | No | | Format exam | ple: 07-August-2008 | |
| Manuscript T | itle: CONSORT 2010 State | ement: Update | d Guidelines for R | eporting Parallel- | Group Randomized | Trials | |
| Manuscript Io | dentifying Number (if y | ou know it): | | | | | |
| Section 2. Infe | ormation about the | support of t | he work unde | er consideration | on for publication | on. | |
| , | r institution at any time res, data monitoring board, | 1 , | 1 1 | , , | | ork (including but no | |
| ☐ No | | | | | | | |
| ∑ Yes, sp | ecify nature of compensat | tion | | | | | |

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| Туре | | y Paid /ou* | Money to Your Institution | | Your | | Your | | Your Name of Entity Comments** | | |
|---|----|----------------|---------------------------------|-----|--|--|-------|--|--------------------------------|--|--|
| | No | Yes | No | Yes | | | | | | | |
| Grant | | | | × | United Kingdom National Health Service; Canadian Institutes for Health Research; Presidents Fund, Canadian Institutes of Health Research; Johnson & Johnson; British Medical Journal; and American Society for Clinical Oncology | | Del× | | | | |
| | | | | | | | Add + | | | | |
| Consulting fee or honorarium | | | | | | | Del × | | | | |
| | | | | | | | Add + | | | | |
| Support for travel to meetings for the study or otherwise | | | | | | | Del × | | | | |
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| | | | | | | | Add + |
| Payment for writing or reviewing the manuscript | | | \boxtimes | | | | Del × |
| | | | | | | | Add + |
| Support in kind such as writing, provision of medicines or equipment, or administrative support | \boxtimes | | | | | | Del × |
| | | | | | | | Add + |
| Other | \boxtimes | | | | | | Del × |
| | | | | | | | Add + |

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|--|-------------|-------------------------|---------------------------------|--------|----------|-------|
| Board membership | \boxtimes | | | | | Del × |
| | | | | | , | Add + |
| Consultancy | \boxtimes | | | | | Del × |
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| Employment | \boxtimes | | | | | Del × |

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|---|-------------|-------------------------|---------------------------------|--------|----------|-------|
| ' | | 1 | | | | Add + |
| Expert testimony | \boxtimes | | | | | Del × |
| | | | | | | Add + |
| Gifts | \boxtimes | | | | | Del × |
| | | | | | | Add + |
| Grants/grants pending | \boxtimes | | | | | Del × |
| | | I | | | | Add + |
| Honoraria | | | | | | Del × |
| Payment for manuscript | | I | | | Г | Add + |
| preparation | | | | | | Del × |
| | | | | | | Add + |
| Patents (planned, pending or issued) | \boxtimes | | | | | Del × |
| | | | | | | Add + |
| Royalties | \boxtimes | | | | | Del × |
| | | | | | | Add + |
| Payment for development of educational presentations including service on speakers' bureaus | | | | | | Del × |
| | | | | | | Add + |
| Stock/stock options | \boxtimes | | | | | Del× |
| | | | | | | Add + |
| Travel/accommodations expenses covered or reimbursed | \boxtimes | | | | | Del × |
| | | | | | | Add + |
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