

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.

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.

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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)
Elisabeth

2. Surname (Last Name)
Dykens

3. Date
23-March-2018

4. Are you the corresponding author? Yes No
Corresponding Author's Name
Michael Reidy

5. Manuscript Title
Intranasal carbetocin reduces hyperphagia in individuals with Prader-Willi syndrome

6. Manuscript Identifying Number (if you know it)
98333

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.

| Name of Entity | Grant? | Personal Fees? | Non-Financial Support? | Other? | Comments |
|--------------------------------------|-------------------------------------|--------------------------|--------------------------|--------------------------|----------|
| National Institutes of Health | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| Foundation for Prader-Willi Research | <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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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. Dykens reports grants from National Institutes of Health, grants from Foundation for Prader-Willi Research, outside the submitted work; .

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) _____ Jennifer _____

2. Surname (Last Name) _____ Miller _____

3. Date _____ 23-March-2018 _____

4. Are you the corresponding author? Yes No Corresponding Author's Name _____ Michael Reidy _____

5. Manuscript Title _____ Intranasal carbetocin reduces hyperphagia in individuals with Prader-Willi syndrome _____

6. Manuscript Identifying Number (if you know it) _____ 98333 _____

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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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 |
|-------------------------|-------------------------------------|--------------------------|--------------------------|--------------------------|------------------|
| Ferring Pharmaceuticals | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | research funding |
| Zafgen | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | research funding |
| Rhythm Pharmaceuticals | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | research funding |

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. Miller reports grants from Ferring Pharmaceuticals, grants from Zafgen, grants from Rhythm Pharmaceuticals, 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)
Moris

2. Surname (Last Name)
Angulo

3. Date
23-March-2018

4. Are you the corresponding author?

Yes No

Corresponding Author's Name
Michael Reidy

5. Manuscript Title

Intranasal carbetocin reduces hyperphagia in individuals with Prader-Willi syndrome

6. Manuscript Identifying Number (if you know it)

98333

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Dr. Angulo 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)

Elizabeth

2. Surname (Last Name)

Roof

3. Date

23-March-2018

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Michael Reidy

5. Manuscript Title

Intranasal carbetocin reduces hyperphagia in individuals with Prader-Willi syndrome

6. Manuscript Identifying Number (if you know it)

98333

Section 2. The Work Under Consideration for Publication

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Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Roof has nothing to disclose.

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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) Michael

2. Surname (Last Name) Reidy

3. Date 23-March-2018

4. Are you the corresponding author? Yes No

5. Manuscript Title
Intranasal carbetocin reduces hyperphagia in individuals with Prader-Willi syndrome

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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 |
|-------------------------------|--------------------------|--------------------------|--------------------------|-------------------------------------|------------------------------------|
| Ferring Pharmaceuticals, Inc. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | salaried employee of study sponsor |

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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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| Patent? | Pending? | Issued? | Licensed? | Royalties? | Licensee? | Comments |
|--|-------------------------------------|--------------------------|--------------------------|--------------------------|-----------|----------|
| Method of treating prader-willi syndrome | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | |

Section 5. Relationships not covered above

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Dr. Reidy reports other from Ferring Pharmaceuticals, Inc., during the conduct of the study; In addition, Dr. Reidy has a patent Method of treating prader-willi syndrome pending.

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4. Intellectual Property.

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

5. Relationships not covered above.

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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)
Hind

2. Surname (Last Name)
Hatoum

3. Date
23-March-2018

4. Are you the corresponding author? Yes No
Corresponding Author's Name
Michael Reidy

5. Manuscript Title
Intranasal carbetocin reduces hyperphagia in individuals with Prader-Willi syndrome

6. Manuscript Identifying Number (if you know it)
98333

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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| Name of Institution/Company | Grant? | Personal Fees? | Non-Financial Support? | Other? | Comments |
|-----------------------------|--------------------------|-------------------------------------|--------------------------|--------------------------|---|
| Ferring Pharmaceuticals | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | consulting arrangement with study sponsor |

Section 3. Relevant financial activities outside the submitted work.

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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

ICMJE Form for Disclosure of Potential Conflicts of Interest

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Section 6. Disclosure Statement

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Dr. Hatoum reports personal fees from Ferring 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) Richard

2. Surname (Last Name) Willey

3. Date 23-March-2018

4. Are you the corresponding author? Yes No Corresponding Author's Name Michael Reidy

5. Manuscript Title Intranasal carbetocin reduces hyperphagia in individuals with Prader-Willi syndrome

6. Manuscript Identifying Number (if you know it) 98333

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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

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| Ferring Pharmaceuticals, Inc. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | salaried employee of study sponsor |

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Dr. Willey reports other from Ferring Pharmaceuticals, Inc., 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) Guy 2. Surname (Last Name) Bolton 3. Date 23-March-2018

4. Are you the corresponding author? Yes No Corresponding Author's Name
Michael Reidy

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

Section 1. Identifying Information

1. Given Name (First Name)
Paul

2. Surname (Last Name)
Korner

3. Date
23-March-2018

4. Are you the corresponding author? Yes No
Corresponding Author's Name
Michael Reidy

5. Manuscript Title
Intranasal carbetocin reduces hyperphagia in individuals with Prader-Willi syndrome

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|-------------------------------|--------------------------|--------------------------|--------------------------|-------------------------------------|------------------------------------|
| Ferring Pharmaceuticals, Inc. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | salaried employee of study sponsor |

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ICMJE Form for Disclosure of Potential Conflicts of Interest

| Patent? | Pending? | Issued? | Licensed? | Royalties? | Licensee? | Comments |
|--|-------------------------------------|--------------------------|--------------------------|--------------------------|-----------|----------|
| Method of treating prader-willi syndrome | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | |

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Dr. Korner reports other from Ferring Pharmaceuticals, Inc., during the conduct of the study; In addition, Dr. Korner has a patent Method of treating prader-willi syndrome pending.

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

| Section/Topic | Item No | Checklist item | Reported on page No |
|----------------------------------|---------|---|-------------------------------------|
| Title and abstract | | | |
| | 1a | Identification as a randomised trial in the title | Word limit for title precludes this |
| | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | 3–4 |
| Introduction | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale | 5–9 |
| | 2b | Specific objectives or hypotheses | 9 |
| Methods | | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | 17 |
| | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | — |
| Participants | 4a | Eligibility criteria for participants | 17 |
| | 4b | Settings and locations where the data were collected | 17 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | 18–19 |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | 19–21 |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | — |
| Sample size | 7a | How sample size was determined | 21 |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | — |
| Randomisation: | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | 17–18 |
| | 8b | Type of randomisation; details of any restriction (such as blocking and block size) | 17–18 |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | 17–18 |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to | 17–18 |

| Section/Topic | Item No | Checklist item | Reported on page No |
|--|---------|---|---|
| Blinding | 11a | interventions If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | 17–18 |
| | 11b | If relevant, description of the similarity of interventions | — |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | 21–22 |
| | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | — |
| Results | | | |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | 10, 32 (Table 1) |
| | 13b | For each group, losses and exclusions after randomisation, together with reasons | 10, 30 (Fig 1) |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | 17 |
| | 14b | Why the trial ended or was stopped | — |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | 32 (Table 1) |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | 10, 32 (Table 1) |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) | 10–12, 31 (Fig 2), 33 (Table 2), 35 (Table S1), 36–39 (Figs S1–4) |
| | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | — |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | — |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | 11–12, 34 (Table 3) |
| Discussion | | | |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | 14–15 |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings | 16 |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | 13–14 |
| Other information | | | |

| Section/Topic | Item No | Checklist item | Reported on page No |
|----------------------|----------------|---|----------------------------|
| Registration | 23 | Registration number and name of trial registry | 4, 17 |
| Protocol | 24 | Where the full trial protocol can be accessed, if available | 4, 17 |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | 2, 4, 24 |

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.