## TREND Statement Checklist

| Paper Section/ Topic | Item No | Descriptor | Reported? ✓ | Reported? Pg # |
|---|---|---|---|---|
| **Title and Abstract** | | | | |
| Title and Abstract | 1 | • Information on how unit were allocated to interventions | X | 1 |
| | | • Structured abstract recommended | X | 2 |
| | | • Information on target population or study sample | X | 2 |
| **Introduction** | | | | |
| Background | 2 | • Scientific background and explanation of rationale | X | 4-5 |
| | | • Theories used in designing behavioral interventions | NA | |
| **Methods** | | | | |
| Participants | 3 | • Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects) | X | 6-7 |
| | | • Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented | X | 6-7 |
| | | • Recruitment setting | X | 6-7 |
| | | • Settings and locations where the data were collected | X | 6-7 |
| Interventions | 4 | • Details of the interventions intended for each study condition and how and when they were actually administered, specifically including: | X | 7-8 |
| | | ○ Content: what was given? | X | 7 |
| | | ○ Delivery method: how was the content given? | X | 7 |
| | | ○ Unit of delivery: how were the subjects grouped during delivery? | X | 6-7 |
| | | ○ Deliverer: who delivered the intervention? | X | 8 |
| | | ○ Setting: where was the intervention delivered? | X | 6-8 |
| | | ○ Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last? | X | 7-8 |
| | | ○ Time span: how long was it intended to take to deliver the intervention to each unit? | X | 7 |
| | | ○ Activities to increase compliance or adherence (e.g., incentives) | NA | |
| Objectives | 5 | • Specific objectives and hypotheses | X | 5 |
| Outcomes | 6 | • Clearly defined primary and secondary outcome measures | X | 6 |
| | | • Methods used to collect data and any methods used to enhance the quality of measurements | X | 6-9 |
| | | • Information on validated instruments such as psychometric and biometric properties | NA | |
| Sample Size | 7 | • How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules | X | 6-9 |
| Assignment Method | 8 | • Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community) | X | 6-9 |
| | | • Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization) | X | 6-9 |
| | | • Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching) | X | 6-9 |

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| | | | | |
|---|---|---|---|---|
| Blinding (masking) | 9 | • Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed. | NA | |
| Unit of Analysis | 10 | • Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community) | X | 6-9 |
| | | • If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis) | X | 6-9 |
| Statistical Methods | 11 | • Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data | X | 8-9 |
| | | • Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis | X | 8-9 |
| | | • Methods for imputing missing data, if used | X | 8-9 |
| | | • Statistical software or programs used | X | 8-9 |
| **Results** | | | | |
| Participant flow | 12 | • Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended) | X | 25 |
| | | ○ Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study | X | 25 |
| | | ○ Assignment: the numbers of participants assigned to a study condition | X | 25 |
| | | ○ Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention | X | 25 |
| | | ○ Follow-up: the number of participants who completed the follow-up or did not complete the follow-up (i.e., lost to follow-up), by study condition | X | 25 |
| | | ○ Analysis: the number of participants included in or excluded from the main analysis, by study condition | X | 25 |
| | | • Description of protocol deviations from study as planned, along with reasons | X | 10 |
| Recruitment | 13 | • Dates defining the periods of recruitment and follow-up | X | 3,6-9 |
| Baseline Data | 14 | • Baseline demographic and clinical characteristics of participants in each study condition | X | 10,30 |
| | | • Baseline characteristics for each study condition relevant to specific disease prevention research | X | 10,31 |
| | | • Baseline comparisons of those lost to follow-up and those retained, overall and by study condition | NA | |
| | | • Comparison between study population at baseline and target population of interest | X | 10,30 |
| Baseline equivalence | 15 | • Data on study group equivalence at baseline and statistical methods used to control for baseline differences | X | 8-10 |

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| | | | | |
|---|---|---|---|---|
| Numbers analyzed | 16 | • Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible | X | 10 |
| | | • Indication of whether the analysis strategy was "intention to treat" or, if not, description of how non-compliers were treated in the analyses | X | 8-9 |
| Outcomes and estimation | 17 | • For each primary and secondary outcome, a summary of results for each estimation study condition, and the estimated effect size and a confidence interval to indicate the precision | X | 10-15 |
| | | • Inclusion of null and negative findings | X | 10-15 |
| | | • Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any | X | 10-15 |
| Ancillary analyses | 18 | • Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory | X | 10-15 |
| Adverse events | 19 | • Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals) | X | 10-15 |
| **DISCUSSION** | | | | |
| Interpretation | 20 | • Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study | X | 15-18 |
| | | • Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations | X | 15-18 |
| | | • Discussion of the success of and barriers to implementing the intervention, fidelity of implementation | X | 15-18 |
| | | • Discussion of research, programmatic, or policy implications | X | 15-18 |
| Generalizability | 21 | • Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other contextual issues | X | 15-18 |
| Overall Evidence | 22 | • General interpretation of the results in the context of current evidence and current theory | X | 15-18 |

*From:* Des Jarlais, D. C., Lyles, C., Crepaz, N., & the Trend Group (2004). Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND statement. *American Journal of Public Health*, 94, 361-366. For more information, visit: http://www.cdc.gov/trendstatement/

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

# 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.

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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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**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): Ed
2. Surname (Last Name): Parsley
3. Date: 18-September-2016

4. Are you the corresponding author? ☐ Yes ☑ No  Corresponding Author's Name:

5. Manuscript Title: Acute hemodynamic effects of inhaled sodium nitrite in pulmonary hypertension associated with heart failure with preserved ejection fraction

6. Manuscript Identifying Number (if you know it): 89620-INS-CMED-RV-2

## 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.

| Name of Institution/Company | Grant? | Personal Fees? | Non-Financial Support? | Other? | Comments |
|---|---|---|---|---|---|
| Aires Pharmaceuticals, Inc. wholly owned subsidiary of Mast Therapeutics, Inc. | ☐ | ☐ | ☐ | ☑ | Full Time Employment |

## 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**.

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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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## 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. Parsley reports other from Aires Pharmaceuticals, Inc. wholly owned subsidiary of Mast Therapeutics, Inc., during the conduct of the study; other from Aires Pharmaceuticals, Inc. wholly owned subsidiary of Mast Therapeutics, Inc., 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): Masataka
2. Surname (Last Name): Sugahara
3. Date: 16-September-2016

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

Corresponding Author's Name: Marc Simon

5. Manuscript Title: Acute hemodynamic effects of inhaled sodium nitrite in pulmonary hypertension associated with heart failure with preserved ejection fraction

6. Manuscript Identifying Number (if you know it): 89620-INS-CMED-RV-2

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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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Dr. Sugahara 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): Timothy
2. Surname (Last Name): Bachman
3. Date: 19-September-2016

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

Corresponding Author's Name: Marc A Simon

5. Manuscript Title: Acute hemodynamic effects of inhaled sodium nitrite in pulmonary hypertension associated with heart failure with preserved ejection fraction

6. Manuscript Identifying Number (if you know it): 89620-INS-CMED-RV-2

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| Name of Institution/Company | Grant? | Personal Fees? | Non-Financial Support? | Other? | Comments |
|---|---|---|---|---|---|
| Mast Therapeutics, Inc. | ☑ | ☐ | ☐ | ☐ | |
| NIH | ☑ | ☐ | ☐ | ☐ | NIH P01HL103455 (MAS, MTG), R01HL098032 (MTG), RO1HL096973 (MTG) |

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Dr. Bachman reports grants from Mast Therapeutics, Inc., grants from NIH,  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): Mehdi
2. Surname (Last Name): Nouraie
3. Date: 18-September-2016

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

Corresponding Author's Name: Marc Simon

5. Manuscript Title: Acute hemodynamic effects of inhaled sodium nitrite in pulmonary hypertension associated with heart failure with preserved ejection fraction

6. Manuscript Identifying Number (if you know it): 89620-INS-CMED-RV-2

## 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.

| Name of Institution/Company | Grant? | Personal Fees? | Non-Financial Support? | Other? | Comments |
|---|---|---|---|---|---|
| NIH | ☑ | ☐ | ☐ | ☐ | NIH P01HL103455 (MAS, MTG), R01HL098032 (MTG), RO1HL096973 (MTG) |

## Section 3. Relevant financial activities outside the submitted work.

Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were **present during the 36 months prior to publication**.

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

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

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

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## Section 5. Relationships not covered above

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

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Dr. Nouraie reports grants from NIH, during the conduct of the study; .

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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
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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): Marc
2. Surname (Last Name): Simon
3. Date: 20-September-2016

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

5. Manuscript Title: Acute hemodynamic effects of inhaled sodium nitrite in pulmonary hypertension associated with heart failure with preserved ejection fraction

6. Manuscript Identifying Number (if you know it): 89620-INS-CMED-RV-2

## Section 2. The Work Under Consideration for Publication

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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 |
|---|---|---|---|---|---|
| Mast Therapeutics, Inc. | ☑ | ☐ | ☐ | ☐ | |
| NIH | ☑ | ☐ | ☐ | ☐ | NIH P01HL103455 (MAS, MTG), R01HL098032 (MTG), RO1HL096973 (MTG) |

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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 |
|---|---|---|---|---|---|
| United Therapeutics | ☐ | ☑ | ☐ | ☐ | |

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# ICMJE Form for Disclosure of Potential Conflicts of Interest

| Name of Entity | Grant? | Personal Fees? | Non-Financial Support? | Other? | Comments | |
|---|---|---|---|---|---|---|
| Gilead | ☐ | ☑ | ☐ | ☐ | | |

## 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. Simon reports grants from Mast Therapeutics, Inc., grants from NIH, during the conduct of the study; personal fees from United Therapeutics, personal fees from Gilead, 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): John
2. Surname (Last Name): Gorcsan III
3. Date:

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

Corresponding Author's Name: Marc Simon

5. Manuscript Title: Acute hemodynamic effects of inhaled sodium nitrite in pulmonary hypertension associated with heart failure with preserved ejection fraction

6. Manuscript Identifying Number (if you know it): 89620-INS-CMED-RV-2

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None

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# ICMJE Form for Disclosure of Potential Conflicts of Interest

## Section 1. Identifying Information

1. Given Name (First Name): Rebecca
2. Surname (Last Name): Vanderpool
3. Date: 19-September-2016

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

Corresponding Author's Name: Marc A Simon

5. Manuscript Title: Acute hemodynamic effects of inhaled sodium nitrite in pulmonary hypertension associated with heart failure with preserved ejection fraction

6. Manuscript Identifying Number (if you know it): 89620-INS-CMED-RV-2

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| NIH | ☑ | ☐ | ☐ | ☐ | NIH P01HL103455 (MAS, MTG), R01HL098032 (MTG), RO1HL096973 (MTG) |

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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): Mark
2. Surname (Last Name): Gladwin
3. Date: 20-September-2016

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

Corresponding Author's Name: Marc Simon

5. Manuscript Title: Acute hemodynamic effects of inhaled sodium nitrite in pulmonary hypertension associated with heart failure with preserved ejection fraction

6. Manuscript Identifying Number (if you know it): 89620-INS-CMED-RV-2

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

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| United Therapeutics | ☑ | ☑ | ☐ | ☐ | |

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|---|---|---|---|---|---|---|
| Bayer | ☑ | ☐ | ☐ | ☐ | | |
| Catalyst Biosciences | ☐ | ☑ | ☐ | ☐ | | |

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| Patent? | Pending? | Issued? | Licensed? | Royalties? | Licensee? | Comments | |
|---|---|---|---|---|---|---|---|
| | ☐ | ☐ | ☑ | ☑ | | Dr. Gladwin is the co-inventor of a US Government patent for the use of nitrite salts for cardiovascular indications | |

## Section 5. Relationships not covered above

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Dr. Gladwin is a co-author of a textbook for medical students published by Medmaster.

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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.

## 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.
**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): Pamela
2. Surname (Last Name): White
3. Date: 19-September-2016

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

5. Manuscript Title
Acute hemodynamic effects of inhaled sodium nitrite in pulmonary hypertension associated with heart failure with preserved ejection fraction

6. Manuscript Identifying Number (if you know it)
89620-INS-CMED-RV-2

## 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.

| Name of Institution/Company | Grant? | Personal Fees? | Non-Financial Support? | Other? | Comments |
|---|---|---|---|---|---|
| Mast Therapeutics, Inc. | ☑ | ☐ | ☐ | ☐ | |
| NIH | ☑ | ☐ | ☐ | ☐ | NIH P01HL103455 (MAS, MTG), R01HL098032 (MTG), RO1HL096973 (MTG) |

## Section 3. Relevant financial activities outside the submitted work.

Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were **present during the 36 months prior to publication**.

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

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

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

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# ICMJE Form for Disclosure of Potential Conflicts of Interest

## 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.

Ms. White reports grants from Mast Therapeutics, Inc., grants from NIH,  during the conduct of the study; .

## Evaluation and Feedback

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