#### **Policies and Procedures**

August, 2017

# Uniform Requirements for Manuscripts Submitted to Biomedical Journals and Other Referenced Guidelines

Southwest Journal of Pulmonary & Critical Care has agreed to follow the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (the "Uniform Requirements") of the International Committee of Medical Journal Editors (ICMJE) (1), the full text of which is available at <a href="http://www.icmje.org">http://www.icmje.org</a>. The manuscript submission instructions set forth at SWJPCC.com are in accordance with the October 2008 version of the Uniform Requirements. Each author is also responsible for fully understanding all requirements listed in this document.

Southwest Journal of Pulmonary & Critical Care has instituted many requirements to address ethical considerations. However, due to the difficulty of anticipating every ethical issue relating to manuscript submission, the list of requirements might not be all-inclusive. Nevertheless, authors' obligation to be ethical is all-inclusive. Before submission, you should ensure that your manuscript, and any research upon which it is based, complies with all of the requirements.

## **Ethics of Publication**

#### Authorship

Following the recommendations contained in the Uniform Requirements (1), Southwest Journal of Pulmonary & Critical Care defines "author" as a person who has participated sufficiently in the work to take public responsibility for all portions of the content. Specifically, an author is a person who:

- 1. Has made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
- 2. Has drafted the submitted article or revised it critically for important intellectual content: and
- 3. Has provided final approval of the version to be published.

Any person who does not meet all three of the listed criteria does not qualify as an author and should not be designated as an author. By way of example, a person does not qualify for authorship by acquiring funding, collecting data, providing technical help or writing assistance, and/or generally supervising the research group.

Those persons who contribute to the submitted manuscript, without qualifying as authors, should be listed (with their written permission) in the Acknowledgments section, together with a description of their individual contributions and institutional affiliations.

All authors must participate in determining the order of authorship before submission (see also "Changing Authorship Post-Submission" below).

The corresponding author is required to provide current e-mail addresses of all coauthors in the cc section of the e-mail during manuscript submission.

# **Contributorship for Original Research**

Southwest Journal of Pulmonary & Critical Care follows the guidelines of the American Medical Association (AMA) (as summarized by Christiansen) (2) and requires that all Original Research papers submitted to Southwest Journal of Pulmonary & Critical Care include an Acknowledgments section that details the role of each of the named authors (does not include case reports); each author should meet these criteria.

## **Responsibility for Data**

For reports containing original data, at least one author (e.g., the principal investigator) must indicate that (s)he had full access to all the data in the study and that he or she takes responsibility for the integrity of the data and the accuracy of the data analysis, including and especially any adverse effects. This statement should appear in the Methods section. The corresponding author is the guarantor, and must assume full responsibility for the integrity of the submission as a whole, from inception to published article. *Southwest Journal of Pulmonary & Critical Care* reserves the right to clarify each author's role, based upon information collected from authors in connection with their submission. For large, randomized, multicenter, controlled trials, different authors may share responsibilities and separately attest to these. Such statements should be provided in the Methods section of the paper. For example:

- For efficacy data: "Dr. XYZ has personally reviewed the efficacy data, understands the statistical methods employed for efficacy analysis, and confirms an understanding of this analysis, that the methods are clearly described and that they are a fair way to report the results."
- For safety data: "Dr. XYZ has personally reviewed the safety data. (S)he
  understands the statistical methods employed for safety analysis and
  confirms that (s)he understands this analysis, that the methods are clearly
  described, and that they are a fair way to report the results." Furthermore,
  (s)he has personally reviewed the Serious Adverse Events occurring in >

- 0.1% of participants per treatment group and confirms that these are fairly disclosed and analyzed even in the presence of uncertainty with respect to relationship to treatment."
- For study design: "Dr. XYZ confirms that the study objectives and procedures are honestly disclosed. Moreover, (s)he has reviewed study execution data and confirms that procedures were followed to an extent that convinces all authors that the results are valid and generalizable to a population similar to that enrolled in this study."

## **Group Authorship**

When authorship is attributed to a group, at least one person should be designated who can take responsibility for the entire manuscript. All individuals named as author(s) for the group study will be required to complete an Author Agreement/Conflict of Interest statement. Other members of the group should be listed in the Acknowledgments section.

# **Avoidance of Ghost Authorship, Guest Authorship, and Guest Writing**

In accordance with the policies of ghost authorship adopted by World Association of Medical Editors (WAME) as outlined at wame.org, authors must acknowledge all persons who have made substantial contributions to writing a manuscript. (See discussion above regarding contributorship.) This requirement covers any and all editorial or authorship contributions made on behalf of outside organizations, persons, funding bodies, or persons hired by funding bodies.

Southwest Journal of Pulmonary & Critical Care also strongly discourages inquiries regarding manuscripts from anyone except the corresponding author or principal investigator. This particularly includes inquires from third-party medical writers and medical writing companies.

## **Changing Authorship Post-Submission**

After a manuscript has been submitted, it is important not to change the authorship list. Corresponding authors should work with their colleagues to ensure the proper list, correct and complete spelling, and the order of authors have been determined before submission. Once a paper has been submitted and the research group decides that an author needs to be added or dropped, the following must be completed:

1. The name to be added or dropped should be provided with an explanation for why the change is occurring.

- 2. All coauthors must provide agreement in writing that they accept this change.
- The role of an added author must be provided (and role played added to the Acknowledgments section of the manuscript in the case of Original Research).
- 4. The Editor in Chief of Southwest Journal of Pulmonary & Critical Care must review the above and agree to the change.
- 5. A Conflict of Interest statement must be provided for an added author.

If the paper is still in review, *Southwest Journal of Pulmonary & Critical Care* reserves the right to begin the review process anew based on the new information. If a paper has been accepted, *Southwest Journal of Pulmonary & Critical Care* reserves the right to rescind the decision and review the paper again.

# **Reporting of Research**

## **Privacy and Informed Consent**

Authors must omit from their manuscripts and figures any identifying details regarding patients and study participants, including patients' names, initials, Social Security numbers, or hospital numbers. If there is a possibility that a patient may be identified in text, figures, or video, authors must obtain written informed consent for use for in publication of print, online, and licensed uses of *Southwest Journal of Pulmonary & Critical Care*, from the patient or parent or guardian and provide copies of the consent forms to *Southwest Journal of Pulmonary & Critical Care*. Authors should indicate in their manuscripts that they have obtained informed consent from patients for their medical data to be used in the manuscript. In addition, all authors are responsible for ensuring that their manuscript and figures comply with the Health Insurance Portability and Accountability Act - HIPAA.

# **Duplicate/ "Salami" Publication**

Submissions will be considered for publication in Southwest *Journal of Pulmonary & Critical Care* only if they are submitted solely to *Journal of Pulmonary & Critical Care* and do not overlap substantially with a published article (3). Any manuscript that has similar or near similar hypothesis, sample characteristics, methodology, results, and conclusions to a manuscript currently in review or press or a published article is a duplicate article and is prohibited. *Journal of Pulmonary & Critical Care* also prohibits so-called "salami" publishing that involves slicing of data collected from a single research process or during a single study period, into different pieces, that form the basis of individual manuscripts published in different journals or the same journal. If any material

related to the submission (other than a brief abstract, meeting abstract, or trials registration) has been published in any medium, is in preparation, or has been submitted or accepted for publication elsewhere, authors must provide copies of all such manuscripts and other materials, as well as outline the relationship of all materials to one another to avoid any possibility of duplicate publication. For this purpose, authors must disclose republication of a paper in another language and publications in journals with a different reader base, as well as articles that relate to the same or similar pool of data described in the submitted article.

The *Journal of Pulmonary & Critical Care* does not treat publication of an abstract as a duplicate publication. Authors should refrain from holding press conferences to publicize their abstract results. You can attach or link electronic copies of any and all published articles or other manuscripts in preparation or submitted elsewhere that are related to the manuscript to be considered by *Journal of Pulmonary & Critical Care*.

# **Preliminary Reporting**

After a submission is accepted for publication in *Journal of Pulmonary & Critical Care*, authors must obtain *Journal of Pulmonary & Critical Care*'s advance approval before reporting any scientific information in their article to public media, governmental agencies, or manufacturers. Please contact Richard A. Robbins at rickrobbins@cox.net or more information. Original Research papers that are posted as Papers in Press cannot be reported on until they have been published in an issue of the Journal.

#### **Using Material from Other Sources**

#### **Permissions**

When use of tables and figures from copyrighted sources is necessary, authors should:

- 1. Obtain permission for all print, online and licensed uses from the copyright holder (usually the publisher);
- 2. Provide copies of the permission with their submissions (use "supplemental material" as the file type when uploading into *Journal of Pulmonary & Critical*;
- Acknowledge the source in the caption;
- 4. Provide the full citation in the reference list; and
- 5. Ensure that any language requirements of the copyright holder have been met (e.g., "Reproduced with permission from XXX"). If the copyright holders ask for payment, it is the responsibility of the authors to pay any fees.

# **Proper Use of Survey Instruments/Questionnaires**

Many papers submitted to *Journal of Pulmonary & Critical Care* are based on survey instruments/questionnaires. It is the responsibility of researchers to know if the survey instrument they use is copyrighted and, if so, to comply with the copyright terms. If a copyrighted survey instrument has been used, authors are responsible for receiving permission to use the survey from the copyright holders. It is generally unacceptable to adapt surveys, and especially unacceptable without the permission of the developer(s) of the survey (4). A copy of the permission to use a copyrighted survey must be attached with the manuscript submission (attach it as "supplemental material" in the file upload area). Surveys that have been translated must be validated and undergo a new psychometric analysis. Authors should confirm that a translated survey has been so validated.

# **Ethics of Investigation**

#### **Ethics**

For all human research, authors must ensure that studies are in accordance with the recommendations found in the Helsinki Declaration of 1975. To do this, one must obtain appropriate informed consent from study participants. For all animal studies, research must conform to National Research Council guidelines (6) as well as local and state regulatory principles or requirements.

#### IRB Approval

An Institutional Review Board (IRB) is a committee formally designated to approve and review research studies involving humans, with the aim of protecting the participants in a study (7). Other names for such committees may be used in some countries.

Investigational protocols must have been reviewed and approved by a formally constituted IRB for human studies (e.g., that the IRB had Assurance from the US Office of Human Protection. Authors are encouraged to provide the Assurance number, which can be applied for and/or found here. Those outside the United States should state that the IRB followed the Helsinki recommendations) (8). Authors should state in their Methods section that they have received IRB approval (and provide the name of the committee and approval number) for their study or have received a statement from the IRB that approval was not necessary for the following reasons: ....When in doubt, authors should obtain IRB approval, even in the case of retrospective studies. In the submission of selected series such as case reports that have no Methods sections, authors

must address the IRB issue in the cover letter to Journal of Pulmonary & Critical Care.

An IRB approval number is not same thing as a clinical trials registration number; the first documents protocols for dealing with participants and the second the design and purpose of a study.

## **Registration of Clinical Trials**

The *Journal of Pulmonary & Critical Care* requires investigators to register their clinical trials in an approved public trials registry. Approved public trials registries are those that meet the criteria established by the World Health Organization (WHO) and/or the ICMJE.

To register a trial, submit the details directly to any one of the WHO primary registries or to an ICMJE approved registry. All approved primary registries of the WHO and those registries approved by the ICMJE can be accessed from that link. *Journal of Pulmonary & Critical Care* requires that clinical trials begun after July 1, 2005, be registered in an approved registry for the paper to be considered for publication. *Journal of Pulmonary & Critical Care* defines a clinical trial according to the ICMJE definition. The most recent editorial on trial registration at icmje.org discusses the evolution of the ICMJE definition of clinical trials.

In June 2007 the ICMJE adopted the WHO's definition of a clinical trial: "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes."

Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes).

Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration.

An IRB statement is not a substitute for an approved clinical trial registration. Journal of Pulmonary & Critical Care reserves the right to decline papers if, in its discretion, it deems the disclosure at the registry to be incomplete. The clinical trial registration number and the place of registry should appear as the last paragraph of the Abstract.

## Study Design

High quality research should be well justified, well planned, and appropriately designed. Outcomes and statistical issues should be addressed and specified at the beginning of the study, and data must be well documented and analyzed according to strict quality control standards. Any fabrication, falsification, concealment, deceptive reporting, or misrepresentation of data constitutes scientific misconduct. *Journal of Pulmonary & Critical Care* may require authors to provide documentation to demonstrate compliance with the requirements described here, as well as the data on which the manuscript is based. It is particularly important that authors report any adverse effects discovered in the course of their investigation and any changes to the protocol that were implemented after the study began.

# **Tobacco Policy**

Journal of Pulmonary & Critical Care will not consider research and manuscripts that have been supported by tobacco companies.

# **Disclosures of Conflicts of Interest (COI)**

Every author must disclose all potential conflicts of interest associated with the manuscript.

A summary statement of COI can be added to the title page of the manuscript.

A COI is a financial relationship or other set of circumstances that might affect, or might reasonably be thought by others to affect, an author's judgment, conduct, or manuscript. A COI exists based on the author's circumstances. The author's behavior, subjective beliefs, and outcomes are irrelevant. In other words, the author must disclose a COI, even if the circumstances do not actually influence the author's actions or manuscript, and even if the author believes that the circumstances cannot or will not affect the author's actions or manuscript.

A good rule of thumb is: when in doubt, disclose. Declaring a COI does not signify that the author has done anything wrong, and it will not preclude publication of a manuscript in *Journal of Pulmonary & Critical Care*. Nevertheless, the COI and its proper disclosure (and, in some cases, elimination) are relevant to the editorial decision. Note, for example, that Editorials present a special case. Because Editorials often contain individual opinions and personal

interpretation of literature and data, authors of Editorials should not have any material financial interest in a company or other organization that makes or supports a product (or competitor of any product) discussed in the Editorial. Failure to disclose a COI is unethical and is prohibited by *Journal of Pulmonary* & *Critical Care*.

If a manuscript is accepted for publication, *Journal of Pulmonary & Critical Care* will determine the parts of an author's disclosures to publish with the manuscript.

# **Copyright Assignment**

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## **Responding to Allegations of Possible Misconduct**

Whenever Journal of Pulmonary & Critical Care has concerns, or receives allegations, of scientific misconduct or other unethical conduct, Journal of Pulmonary & Critical Care reserves the right to proceed according to the procedures described below and to the guidelines issued by the Office of Research Integrity (ORI) (9) Journal of Pulmonary & Critical Care recognizes its responsibility to appropriately address concerns and allegations of misconduct that are known or brought to Journal of Pulmonary & Critical Care's attention.

Journal of Pulmonary & Critical Care's policy and procedures cover all types of misconduct. Some examples of misconduct include falsification of data, plagiarism (both plagiarism of others and self-plagiarism), improper designations of authorship, duplicate publication, misappropriation of others' research, failure to disclose conflicts of interest, and failure to comply with applicable legislative or regulatory requirements. Misconduct also includes failure to comply with any of Journal of Pulmonary & Critical Care's other ethical rules and policies not specifically enumerated here, and other behaviors specified in the ORI guidelines (9).

All concerns or allegations of misconduct will be reviewed by the editors. If the allegations are thought to have merit, the editors will request from all of the involved parties a written explanation of the circumstances surrounding the potential misconduct, and may consult experts who are blinded to the identity of the individuals and institutions involved. The goal will be to determine whether there is a reasonable possibility of misconduct.

Journal of Pulmonary & Critical Care's Editor in Chief has final authority to respond to any reasonable possibility of misconduct. Responses may vary depending on the apparent severity of possible misconduct, the surrounding circumstances, and responses received from the individuals and institutions involved. Responses may include one or more of the following:

- Sending a letter of explanation only to the person(s) involved or against
  whom the allegation is made. This response might be appropriate if the
  person(s) seemed to have acted with a genuine and innocent
  misunderstanding of policy or procedure.
- Sending a letter of reprimand to the same person(s), warning of the consequences of future, similar instances. This response might be appropriate if the misunderstanding of policy or procedure appears to be not entirely innocent.
- Sending a letter to the relevant head of the educational institution and/or financial sponsor of the person(s) involved, expressing *Journal of Pulmonary & Critical Care*'s concerns and including the information collected. This response might be appropriate if actual misconduct seems probable, in which case a formal review and determination are advisable. *Journal of Pulmonary & Critical Care* might request a written report of the findings of the investigation.
- Publishing in *Journal of Pulmonary & Critical Care* a notice of duplicate publication, "salami" publishing, plagiarism, or other misconduct, if unequivocally documented. In cases of ghost-written manuscripts, the notice may include the names of the responsible companies as well as the submitting author(s).
- Providing specific names to the media and/or government organizations, if contacted regarding the misconduct.
- Formally withdrawing or retracting the manuscript at issue from *Journal of Pulmonary & Critical Care*, and informing readers, if an institution makes a formal finding of misconduct.
- Banning an author or authors from publishing any manuscript in *Journal of Pulmonary & Critical Care* for a specified time period, with notice to the author(s)' institution.

# Manuscript Handling

## **Tracking and Correspondence**

Receipt of a manuscript is acknowledged via e-mail from the Editorial Office through the *Journal of Pulmonary & Critical Care*. Each submission is assigned a manuscript tracking number that will appear in the e-mail. Please provide this tracking number on all correspondence regarding the manuscript. Although all

authors are copied on decision letters, only the corresponding author should communicate with the *Journal of Pulmonary & Critical Care* regarding the manuscript.

#### **Peer Review**

All submissions are subject to peer review. *Journal of Pulmonary & Critical Care* will send manuscripts to outside reviewers selected from an extensive database. Authors are encouraged to provide the names of particularly qualified reviewers who have had experience in the manuscript subject, but who are not affiliated with the same institution(s) as the author(s). Authors may also suggest names of individuals who they would prefer not to review their paper. *Journal of Pulmonary & Critical Care* reserves the right to make the final selection of peer reviewers. *Journal of Pulmonary & Critical Care* also reserves the right, in its discretion, to determine the number and kind of manuscripts sent for review, the number of reviewers, the reviewing procedures, and the use made of reviewer's opinions. In addition to scientific merit, the Editor in Chief reserves the right to evaluate papers without external peer review based on the Editor in Chief's opinion on how well the subject matter relates to the interest of readers of *Journal of Pulmonary & Critical Care*. Effort is made to complete the review process in a timely manner.

# **Manuscript Editing**

All accepted manuscripts are subject to copyediting for conciseness, clarity, grammar, spelling, and *Journal of Pulmonary & Critical Care* style. The corresponding author will receive page proofs to review before publication. If authors request changes after they have returned corrected proofs, a handling fee will be assessed. Care should be exercised in this stage of review so as to avoid publication of errata or retractions.

# Reprints

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