

# AAPS ELECTRONIC JOURNALS ETHICS POLICY

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## Introduction

The American Association of Pharmaceutical Scientists (AAPS) has developed this ethics policy to guide decision-making for the AAPS Electronic Journals, *The AAPS Journal* and *AAPS PharmSciTech*. The document is based on the recommendations on publication ethics policies for medical journals published by the World Association of Medical Editors (WAME), posted at <http://wame.org/resources/ethics-resources>, and subscribed to by almost 1,000 journals. In addition, Springer's Policy on Publishing Integrity for *Pharmaceutical Research* was used as a starting-point for the development of this policy. A major consideration was that the Official AAPS Journals should have consistent responses that can be implemented fairly in cases of ethical breaches by authors, reviewers, or editors.

This policy paper contains two sections. Part I addresses issues for editors, authors and reviewers, while Part II outlines AAPS' procedures in cases of suspected ethical misconduct.

## I. PUBLICATION ETHICS FOR THE AAPS JOURNALS

The AAPS Journals ethics policy deals with the following:

1. Human subjects and animal use;
2. Data fabrication or falsification;
3. Proper identification of authors and their contributions;
4. Plagiarism;
5. Duplicate or simultaneous submission or publication of research results;
6. Conflicts of interest (author);
7. Image acquisition and preparation
8. Editorial conflicts of interest and peer review policies;
9. Advertising;
10. Media relations; and
11. Other professional misconduct

## II. AAPS POLICY IMPLEMENTATION PROCEDURES FOR THE EDITORS-IN-CHIEF

The AAPS procedures, adapted from the AMA Style Guide, 10<sup>th</sup> Edition, are organized as follows:

1. AAPS response to allegations of breaches of its publications ethics policy; and
2. AAPS procedures in cases of suspected ethical misconduct.

[AAPS Electronic Journals Ethics Policy revision approved by the AAPS Executive Council, January 12, 2011.]

## **I. PUBLICATION ETHICS FOR THE AAPS JOURNALS**

### **1. Human Subjects and Animal Use**

#### **1.1. Human Subjects**

AAPS Journals require a statement by the author(s), at the time of manuscript submission, indicating documented review and approval from a formally constituted review board (Institutional Review Board or Ethics committee) for all studies involving people, medical records, and human tissues, per the uniform guidelines from the World Medical Association ([www.wma.net/e/policy/b3.htm](http://www.wma.net/e/policy/b3.htm)).

The AAPS Journals require that controlled clinical trials be registered in a publicly available database or the Journals, at the Editors' discretion, may decide not to publish the results of these trials. For this purpose, the AAPS defines a clinical trial as any research project that prospectively assigns human subjects to intervention or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Studies designed for other purposes, for instance proof of principle or concept studies on pharmacokinetics, pharmacodynamics or toxicity end-points (e.g., Phase 1 trials), would be exempt. Manuscripts submitted to the Journals should include trial registration information in the cover letter. To register a clinical trial, authors should go to the NIH registry ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)) or the International Standard Randomized Controlled Trials database (<http://isrctn.org>). Further information can be obtained from the International Committee of Medical Journal Editors (ICMJE) at <http://www.icmje.org/faq.pdf>, or by contacting the Editor of the Journal to which the authors wish to submit their manuscript.

#### **1.2. Animal Use**

AAPS Journals require a statement by the author(s), at the time of manuscript submission, indicating that animal experiments are conducted in full compliance with local, national, ethical, and regulatory principles and local licensing regulations, per the spirit of Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International's expectations for animal care and use/ethics committees ([http://www.aaalac.org/education/module\\_1.cfm](http://www.aaalac.org/education/module_1.cfm)).

### **2. Data Fabrication or Falsification**

AAPS Journals consider the following as serious scientific misconduct: the deliberate fabrication of data, including images, deceptive selective reporting of findings, omission of conflicting data, or willful suppression and/or distortion of data. Whether such alleged misconduct occurred during the peer review process or after publication of an accepted article, AAPS policy requires that there will be a formal response with substantial consequences, including retraction of published paper(s) and/or embargo on future publication in AAPS Journals, for authors who are found to have breached the accepted standards for data reporting.

*[AAPS Electronic Journals Ethics Policy revision approved by the AAPS Executive Council, January 12, 2011.]*

### **3. Proper Identification of Authors and Their Contributions**

AAPS uses the guidelines developed by the ICMJE (available at [www.icmje.org/#author](http://www.icmje.org/#author)) in defining authorship. Early in the research process, the participants should determine who will be listed as authors and in what sequence, to avoid later conflict.

To be listed as an author of an article submitted to or published in an AAPS Journal, an individual must have contributed intellectually and substantially to the work described, must have reviewed and approved the submitted manuscript, and must commit to taking responsibility for the overall scientific validity of the work. An author's contribution may take various forms, including conceptualization, conduct, data interpretation and presentation, and/or direction of part or the entire research project. If writers are provided by the sponsoring or funding institution or corporation to draft or revise the article, the name of the writer and his or her sponsoring organization must be provided within the acknowledgments.

All authors of articles submitted to the AAPS Journals are responsible for the quality, accuracy, and ethics of the work, but one author (the "corresponding author") must be identified as the contact for questions or additional information. The corresponding author also commits to being the guarantor of the article's compliance with the AAPS ethical policy and to taking responsibility for the work as a whole.

### **4. Plagiarism**

AAPS defines plagiarism as the use of others' published and unpublished ideas or words (or other intellectual property) without attribution or permission, and presenting them as new and original rather than derived from an existing source. Such sources include abstracts, research grant applications, Institutional Review Board applications, or unpublished or published manuscripts in any publication format (print or electronic). AAPS action concerning documented plagiarism may include public disclosure of such violation, retraction of plagiarized paper(s), and/or embargo on future publication in AAPS Journals. AAPS will cooperate with the author's institution in its investigation of such violations.

Self-plagiarism refers to the practice of an author using portions of his or her previous writings on the same topic in another article, without specifically quoting or citing the self-plagiarized material. AAPS strongly discourages such unacknowledged self-plagiarism, and may take action against such violation when appropriate.

### **5. Duplicate or Simultaneous Submission or Publication of Research Results**

AAPS requires authors who submit papers to any of the AAPS Journals to acknowledge and agree that results presented as new data have not been published and are not being considered for publication elsewhere. It is generally agreed that preliminary work on

which the paper is based may have been presented as a poster or as an abstract at one or more scientific conferences.

Duplicate or simultaneous submission that is discovered during the peer review process or after acceptance of the duplicate paper will result in an official AAPS communication to the author's institution, possible retraction and ban from further publishing in the AAPS Journals in the future.

## **6. Conflicts of Interest (Author)**

Conflicts (duality) of interest may influence the judgment of authors, reviewers, and editors, and may mislead readers. The perception of conflict of interest is nearly as important as an actual conflict, since both erode trust. Conflicts may be financial, academic, commercial, political or personal. Financial interests may include employment, research funding (received or pending), stock or share ownership, patents, payment for lectures or travel, consultancies, nonfinancial support, or any fiduciary interest in a company.

Authors must declare all such interests (or their absence) in writing upon submission of a manuscript. This conflict declaration includes conflicts or potential conflicts of all listed authors. If any conflicts are declared, AAPS will publish them with the paper. In cases of doubt, the circumstance should be disclosed so that the editors may assess its significance.

Sources of full or partial funding or other support for the research must be declared and should be described in an acknowledgement if the manuscript is published, as must the role of the funding organization or sponsor in the design and conduct of the study, in the collection, analysis, and interpretation of the data, and in the preparation, review, or approval of the manuscript. If anyone besides the named authors is involved in analysis, interpretation or control of the data, this must also be declared.

Manuscripts authored or coauthored by the Editor-in-Chief present a special instance of potential conflict of interest. The review of these manuscripts in the AAPS Journals will insulate the editor/author from the review process (using features of the web-based submission and peer review system, Editorial Manager™). Specifically, the Chair of the AAPS Publications Committee will be given "guest editor" status to handle selection of reviewers and the review process for papers authored or coauthored by the Editors-in-Chief, who will be permanently blinded to the reviewers and the record of their papers. In the event the Chair of the Publications Committee believes the paper's subject matter is outside his or her realm of expertise, he or she may appoint a member of the Publications Committee or other qualified person as Guest Editor. For papers authored or coauthored by Associate Editors and others closely associated with the decision-making process for the journal, the Editor-in-Chief will handle the review process, but should a conflict arise, the Chair or a member of the Publications Committee may be called upon to serve as a Guest Editor.

## **7. Image Acquisition and Preparation**

The AAPS policy on image acquisition and preparation requires that no specific feature of an image may be enhanced, obscured, moved, removed, or introduced. The Information for Authors for each of the AAPS Journals includes specific details on technical requirements for image acquisition and preparation. If, after the manuscript is accepted, manipulation of one or more images is suspected, the Editor-in-Chief of the Journal may request the original data from the authors for comparison with the submitted figures. If the author cannot produce the original data, the acceptance of the manuscript may be revoked.

## **8. Editorial Conflicts of Interest and Peer Review Policies**

The AAPS policy on Conflict of Interest requires annual disclosure of Conflicts of Interest (financial, academic, commercial, political or personal) by all members of the Journals' editorial teams, including Editors-in-Chief, Deputy, Field, Section, and Associate Editors. These disclosure statements will be kept on file and available upon written request and approval by the AAPS Executive Director.

Reviewers must disclose financial, academic, commercial, political or personal conflicts of interest for specific papers and should recuse themselves when they have conflicts that could be viewed as biasing their judgment of the merits or lack of merits of a particular paper. A reviewer should not be employed at the same institution as any of the authors of a submitted paper.

Reviews of papers submitted to the AAPS Journals are expected to be professional, honest, courteous, prompt, and constructive. The desired major elements of a high-quality review are:

- The reviewer should have identified and commented on the major strengths and weaknesses of the study rationale, design and methodology
- The reviewer should comment accurately and constructively upon the quality of the author's experimental work and data interpretation, including acknowledgment of its limitations.
- The reviewer should comment on the major strengths and weaknesses of the manuscript as a written communication, independent of the design, methodology, results, and interpretation of the study.
- The reviewer should provide the author with useful suggestions for improvement of the manuscript.
- The review should provide the editor the proper context and perspective to make a decision on acceptance (and/or revision) of the manuscript.

The submitted manuscript is a privileged communication; reviewers must treat it as confidential. It should not be retained or copied, nor should it be shared with any

colleagues without the explicit permission of the editor. Reviewers and editors must not make any personal or professional use of the data, arguments, or interpretations (other than those directly involved in its peer review) prior to publication unless they have the authors' specific permission or are writing an editorial or commentary to accompany the article.

Referees are prohibited from using confidential information learned in the course of their review in a manner inconsistent with copyright, patent, or other proprietary rights learned in the course of review.

If reviewers suspect scientific misconduct or have ethical concerns, they must notify the editor in confidence and should not share their concerns with other parties unless officially notified by the journal that they may do so.

## **9. Advertising**

Advertisements may not be deceptive or misleading. Exaggerated or extravagantly worded copy should not be allowed. Advertisements should not be accepted if they appear to be indecent or offensive in either text or artwork, or contain negative content of a personal, racial, ethnic, sexual orientation, or religious character.

The AAPS Journals have the right to refuse any advertisement for any reason.

## **10. Media Relations**

The AAPS Public Outreach Department has the authority to embargo news or press releases on a case-by-case basis per standard public relations practices. This is the process by which the media is given advance knowledge of information, typically related to data being presented at an AAPS meeting or workshop, provided it not be published until a certain date or certain conditions have been met.

## **11. Other Professional Misconduct**

The Editors-in-Chief, in consultation with AAPS, will consider, from time to time, revisions of these guidelines to comply with evolving standards.

## II. AAPS POLICY IMPLEMENTATION PROCEDURES FOR THE EDITORS-IN-CHIEF

### 1. AAPS Response to Allegations of Breaches of its Publications Ethics Policy

The goals of the AAPS' policy on responding to allegations of author or reviewer misconduct are to ensure that the reputation of the journal in question is protected; to ensure that readers can continue to have the highest level of confidence in the AAPS Journals; to correct the scientific record by disclosing proven or admitted breaches and by removing content from the journals that is the result of plagiarism or other scientific misconduct; to educate authors about the need for scrupulous adherence to the principles and practices of ethical publication; to protect authors who are wrongly accused of breaches of ethics; to censure and prevent future violations by authors who have committed breaches of these policies; and to ensure that the AAPS is not, as an organization, negatively impacted.

The steps taken to reach these goals are as recommended in the 10<sup>th</sup> edition *AMA Manual of Style*, © American Medical Association 2006–2007, 5.4.4 and adapted below for AAPS:

*“If an allegation of scientific misconduct is made in relation to a manuscript under consideration or published, the editor has a duty to ensure confidential and timely pursuit of that allegation... but the editor is not responsible for conducting the investigation.*

*“An editor's first step after receiving an allegation of falsified, fabricated, or plagiarized work published in her or his journal is to consider contacting the corresponding author, depending on the circumstances, to request an explanation, while maintaining confidentiality... if guilt is admitted, the editor should request a letter of formal retraction from the author (preferably signed by the author and all coauthors); the editor should also notify the author's institution and inform the author of this notification.*

*“If the explanation allays any concerns about misconduct, the editor may need to publish some form of correction or clarification or otherwise inform the person making the allegation that no misconduct has occurred. If the explanation is not satisfactory, or leads to additional concerns, or no explanation is received, the editor should contact the author's institutional authority to request a formal investigation and should notify the author of this plan.*

*“The responsibility to conduct an investigation lies with an authority at the author's institution where the work was done (e.g., dean, president, or ethical conduct/research integrity officer), with the funding agency, or with a national agency charged to investigate such allegations, such as the US Office of Research Integrity in the United States, the UK's Medical Research Council, or the Danish Committees on Scientific Dishonesty.... The editor cannot conduct the investigation because he or she does not have the appropriate institutional access or an employment relationship with the author*

*or other relationship such as that between the author and a governmental funding agency...*

*“The editor should take great care to maintain confidentiality during any communication about the allegation....editors should avoid including details of the cases in e-mails that can be widely circulated and should avoid posting details, even if rendered anonymous, in e-mail lists or blogs.”*

If the author is not formally employed by any institution, the Editor-in-Chief should refer the matter to the AAPS Publications Committee for its consideration and action.

## **2. AAPS' Procedures in Cases of Suspected Ethical Misconduct**

AAPS has developed the following procedures for dealing with cases of suspected ethical misconduct by authors in its journals, *The AAPS Journal* and *AAPS PharmSciTech*. Information about similar procedures for *Pharmaceutical Research* may be obtained from the Publisher, Springer. In keeping with its commitment to best practices in journal publishing, AAPS utilized the resources of the World Association of Medical Editors (WAME), the International Committee of Medical Journal Editors (ICMJE), and the Council on Publishing Ethics (COPE) in the development of both its policy regarding scientific misconduct and its procedures for dealing with suspected cases. Note that the identity of the author(s), reviewer(s) and accuser(s) will be kept confidential at all times during the review of cases. Only when a public announcement, such as a retraction, is formulated, at the conclusion of the procedures, will the identity of the author(s) be made public.

### **2.1. Procedures at Initiation of Inquiry**

2.1.1. When one of the Editors identifies or receives an allegation of ethical misconduct concerning a submitted, accepted, or published manuscript, the allegation must be formally recorded in writing with details of the accuser, the manuscript under suspicion, and the alleged problem or concern.

2.1.2. Determination of a *prima facie* case of ethical misconduct is made by an ad hoc editorial committee of the journal.

### **2.2. Procedures after Initial Determination**

2.2.1. If the ad hoc committee determines that the allegation does not establish a *prima facie* case for ethical misconduct, the Editor will let the accuser know the committee's determination and that no further action will be taken.

2.2.2. If the ad hoc committee finds that there is a *prima facie* case for ethical misconduct, the Editor sends a confidential letter to the corresponding author requesting a formal letter of explanation regarding the allegation, which should be received by the Editor within fourteen (14) days. Authors may not know the identity of the accuser

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unless otherwise decided by the Editor. In any event, it is incumbent upon the corresponding author to cooperate fully with the Editor.

### **2.3. Procedures upon Receipt (or Not) of the Corresponding Author's Response**

2.3.1. The corresponding author's response will be reviewed by the ad hoc editorial committee, whereupon all listed authors on the paper, as well as the original complainant, will either be informed that the explanation is satisfactory, with no additional action needed by either party OR

2.3.2. If the ad hoc committee determines that ethical misconduct appears to have occurred, or the author(s) fail(s) to submit a letter of explanation within a reasonable length of time, the Editor shall take one of the following actions:

- (a) If the misconduct is admitted, the Editor will publish a retraction or other statement, e.g., Note of Concern, in the Journal OR
- (b) If the author(s') original response to the Editor maintained that there was no engagement in ethical misconduct, then the Editor prepares an official assessment of the validity of the allegation and the accused author(s') explanation to the AAPS President, Publications Committee Chair and Executive Director for further review and decision OR
- (c) Likewise, if no formal letter of explanation from the author(s) is received, even after repeated requests, the Editor prepares an official assessment and distributes it as in 2.3.2.(b).

### **2.4. Decision about Misconduct**

2.4.1. The AAPS President, Publications Committee Chair and Executive Director review Editor's assessment and, in consultation with Editor and AAPS Legal Counsel, will arrive at a decision. However, if an ethical misconduct case involves **suspected data fabrication or falsification**, AAPS will request a formal investigation be completed by the author(s') institution(s) by a specified deadline, allowing AAPS to move forward with one of the following steps in a timely manner:

- (a) If misconduct is found, the author(s) will be asked to submit a formal retraction or withdrawal letter, with appropriate timelines. If the case does not involve data fabrication or falsification, but some other misconduct, e.g., plagiarism, a letter will be sent to the author(s') institution(s), which will include details of the case with AAPS' decision and will serve as a notification of the decision and subsequent action on behalf the Journal; any formal investigation of the author or authors by the institution(s) is left to the institution(s) involved. OR
- (b) If misconduct is found, and the author(s) fail(s) to submit a formal letter of explanation after repeated requests from the Editor, AAPS will take the actions listed below in section 2.5.1. OR
- (c) If a determination is made that the allegation does not establish a case of ethical misconduct, that determination will be communicated to the author(s) and accuser and

no further action will be taken.

## **2.5. In the Event Retraction is Refused or Reconsideration of the Decision is Requested**

2.5.1. If misconduct is found but the author(s) do not voluntarily retract or withdraw the paper, or fail to respond to the Editor, AAPS will take action on the allegation of misconduct, which may include requesting that the institution retract the paper, deciding that AAPS will retract the paper on behalf of the journal, or publishing a Note of Concern in the Journal. Additional penalties are possible, e.g., banning author(s) from publishing in the journal for a set period or for life.

2.5.2. If in the course of continued denial of any wrongdoing or once a penalty has been assessed by AAPS, an accused author requests reconsideration of the decision, it will be incumbent upon the author to provide further evidence to AAPS. Specifically, the author must provide additional information to the signatories of the communications, supporting the position that no wrongdoing has taken place. Failing such submission of further evidence, the matter will be closed, and the AAPS' decision will be deemed final.