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ETHICAL PRACTICE GUIDELINES IN ADDICTION PUBLISHING: A MODEL FOR AUTHORS, JOURNAL EDITORS AND OTHER PARTNERS

ISAJE ETHICS COMMITTEE

1.0 STATEMENT OF PURPOSE

The purpose of this document is to enhance the quality and protect the integrity of scientific publishing in addiction specialty journals. It is written in the interests of all those who engage in the scientific endeavor and those who put trust in the truthfulness of the scientific output. To that end, this document provides guidance to authors, editors and other individuals regarding ethical and procedural issues that affect the integrity of scientific publishing.

These guidelines were developed to deal with the growing complexity of decision-making in addiction journal publishing, which often requires critical judgment on the part of editors, reviewers, authors, publishers and others with regard to ethical issues. The guidelines address two broad areas: 1) the responsibilities of authors, and 2) the responsibilities of editors, journal staff and journal owners.

These guidelines are presented as an idealized version of good ethical practice, and do not necessarily represent the policies of the ISAJE member journals. There may be national and cultural considerations that influence the applicability of some of these guidelines to individual journals. The guidelines should therefore be considered provisional. They are intended to be adapted to the needs of individual journals and authors, and should be modified with experience and expanded when necessary to include new challenges to ethical decision-making. We hope that they will be used by editors, disseminated widely, and refined by those who use them.

2.0 How the guidelines were developed

Published and unpublished editorial guidelines and codes of ethics were obtained from the biomedical literature and other sources. An important starting point was the work of the International Committee of Medical Journal Editors, the World Association of Medical Journal Editors and the Committee on Publication Ethics (COPE). COPE was established in 1997 to address breaches of research and publication ethics. A voluntary body providing a discussion forum and advice for scientific editors, it developed a set of "guidelines on good publication"

practice" that apply to editors, authors and other people involved in scientific publishing. The COPE Guidelines were adapted by one of the ISAJE member journals, Drug and Alcohol Dependence, and this modified code was also consulted. The Farmington Consensus, a set of principles drafted by representatives of addiction journals, were reviewed, as were publications on research ethics and conflict of interest drafted by the U.S. National Institutes of Health, Office of Research Integrity and by the "Integrity in Science" project of the Center for Science in the Public Interest (CSPI). A complete bibliography of sources consulted by the ISAJE Ethics Committee is provided at the end of this document. The following acronyms indicate definitions or guidelines in the text that have been adopted more or less verbatim from a previous document:

COPE Committee on Publication Ethics

FARM Farmington Consensus

DAD Drug and Alcohol Dependence

ORI Office of Research Integrity, US National Institutes of Health

CSPI Center for Science in the Public Interest

3.0 RESPONSIBILITIES OF AUTHORS

The responsibilities of authors include but are not limited to study design, ethical approval of research, data analysis, authorship credits, conflict of interests, redundant publication, and plagiarism.

3.1 Study Design and Ethical Approval

3.1.1 Definition or Principle

Research reported in addiction journals should be well justified, well planned, appropriately designed, ethically approved (COPE 2001), scrupulously analyzed and honestly interpreted.

3.1.2 Guidelines

- 3.1.2.1 Formal and documented ethical approval from an appropriately constituted research ethics committee is required for all studies involving people, medical records, and, where required, anonymised human tissues (COPE 2001).
- 3.1.2.2 Fully informed consent should always be sought. It may not always be possible, however, and in such circumstances, an appropriately constituted research ethics committee should decide if this is ethically acceptable (COPE 2001).
- 3.1.2.3 When participants are unable to give fully informed

consent, research should follow international guidelines, such as those of the Council for International Organizations of Medical Sciences (COPE 2001).

3.1.2.4 Animal experiments require full compliance with local, national, ethical, and regulatory principles, and local licensing arrangements. International standards vary (COPE 2001).

3.1.2.5 Formal supervision, usually the responsibility of the principal investigator, should be provided for all research projects: this must include quality control, and the frequent review and long-term retention of all records and primary outputs (COPE 2001).

3.2 Authorship Credits

3.2.1 Definition or Principle

Authorship of a scientific report refers to the origin of a literary production, not just to the experimentation, data collection or other work that led up to it. All persons named as authors should 1) have made a major contribution to the work reported, and 2) be prepared to take public responsibility for its contents.

According to an Editorial in the Annals of Internal Medicine: "Responsibility means the ability and willingness to defend the content of the paper if it is challenged by readers. Public means that authors are willing to carry out this responsibility in a published defense, such as a signed letter to the editor; private defense in private correspondence would not reach the scientific public. Content means not simply packages of data but also the conceptual framework on which they are hung: the justification for a study or clinical observations; the basis for the study design; methods for collection of valid data: the analysis and interpretation of the data; and the logic that led to the conclusions" (Editor, 1982, p. 613).

3.2.2 Guidelines

3.2.2.1 Early agreement on the precise roles of the contributors and collaborators, and on matters of authorship and publication, is advised (COPE 2001). All contributors to a research project or other scholarly publication should be advised of their authorship responsibilities and given the opportunity to participate in the drafting of the manuscript. Initial inclusion in the planning of a scientific paper does not necessarily warrant authorship credit unless the prospective author makes a substantive contribution as described below. The lead author should periodically review the

status of authorship credits and substantive contributions with all prospective collaborators, in order to avoid disputes.

3.2.2.2 The award of authorship should balance intellectual contributions to the conception, design, analysis and writing of the study against the collection of data and other routine work. If there is no task that can reasonably be attributed to a particular individual, then that individual should not be credited with authorship (COPE 2001). All listed authors on a paper should have been personally and substantially involved in the work leading to the paper (FARM 1997). Involvement in data collection and other routine tasks does not necessarily warrant authorship credit. Similarly, merely granting access to clinical samples or being the head of a research unit or grant is not by itself sufficient to justify a share in authorship.

- 3.2.2.3 All authors must take public responsibility for the content of their paper. The multidisciplinary nature of many research studies can make this difficult, but this can be resolved by the disclosure of individual contributions (COPE 2001).
- 3.2.2.4 If professional writers employed by pharmaceutical companies, medical agencies, or other parties have written the paper, then their names should be included, and any conflicts of interest declared (COPE 2001).
- 3.2.2.5 Authors should not allow their name to be used on a piece of work merely to add credibility to the content (COPE 2001).

3.3 Redundant Publication

3.3.1 Definition or Principle

Redundant publication occurs when two or more papers, without full cross-reference, share any of the same data (COPE 2001; DAD 2000). Authors are expected to ensure that no significant part of the submitted material has been published previously and that it is not concurrently being considered by another journal. An exception to this general position may be made when previous publication has been limited to another language, to local publication in report form, or to publication of a conference abstract.

3.3.2 Guidelines

3.3.2.1 Publication in different papers of subsets of data from the same population of subjects in a study may be acceptable if

publication in one article would render it unreasonably long and complex. In such cases, cross-referencing to the other relevant publication(s) must occur (DAD 2000).

- 3.3.2.2 Previous publication of an abstract during the proceedings of meetings does not preclude subsequent submission for publication, but full disclosure should be made at the time of submission (COPE 2001).
- 3.3.2.3 Re-publication of a paper in another language is acceptable, provided that there is full and prominent disclosure of its original source at the time of submission (COPE 2001) and provided that any necessary copyrights are respected.
- 3.3.2.4 At the time of submission, authors should disclose details of related papers, even if in a different language, and similar papers in press (COPE 2001). When in doubt, authors should provide the editor at the time of submission with copies of published or submitted reports that are related to that submission.

3.4 Plagiarism

3.4.1 Definition or Principle

Plagiarism ranges from the unreferenced use of others' published and unpublished ideas, including research grant applications, to submission under "new" authorship of a complete paper, sometimes in a different language. It may occur at any stage of planning, research, writing, or publication; it applies to print and electronic versions.

3.4.2 Guidelines

3.4.2.1 All sources should be disclosed through appropriate citation or quotation conventions, and if a large amount of other people's written or illustrative material is to be used, permission must be sought (COPE 2001). Legal definitions may vary from country to country regarding plagiarism, copyright and intellectual property rights. These should be reviewed with the editor when there is any question.

3.5 Conflict of Interest

3.5.1 Definition or Principle

A conflict of interest is a situation or relationship in which professional, personal, or financial considerations could be seen by a fair-minded person as potentially in conflict with independence of judgement (FARM 1997). It has also been described as a situation or relationship which, when revealed later, would make a reasonable reader feel misled or deceived. A conflict may be personal, commercial, political, academic or financial. "Financial" interests may include employment, research funding, stock or share ownership, payment for lectures or travel, consultancies, and company support for staff (COPE 2001). Conflict of interest is not in itself wrongdoing (FARM 1997). The potential for conflict of interest in the addiction field is enhanced by any relationship or funding connected with the tobacco industry, the alcohol beverage industry, for-profit health care systems, private hospitals, the pharmaceutical industry, and "social aspect organizations" that receive their primary support from these sources.

There are three levels of conflict of interest: real, apparent, and potential. A real conflict of interest means that the author, or the administrative unit with which the author has an employment relationship, has a financial or other interest that could unduly influence the author's position with respect to the subject matter being considered. An apparent conflict of interest exists when an interest would not necessarily influence the author but could result in the author's objectivity being questioned by others. A potential conflict of interest exists with an interest that any reasonable person could be uncertain whether or not it should be reported.

3.5.2 Guidelines

3.5.2.1 Each author should declare to the editor any interests that could constitute a real, potential or apparent conflict of interest with respect to his/her involvement in the publication, between (1) commercial entities and the participant personally, and (2) commercial entities and the administrative unit with which the participant has an employment relationship. "Commercial entity" refers to any company, association (e.g., trade association), organization, or other unit with commercial interests.

3.5.2.2 Although conflict of interest policies may differ among journals, at a minimum declarations to the editor should cover significant financial or other relations (e.g., consulting, speaker fees) of the author with companies, trade associations, unions, or groups (including civic associations and public interest groups) that may gain or lose financially from the results or conclusions in the study, review, editorial, or letter (CSPI 2002).

3.5.2.3 All sources of funding for the study, review, or other item

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should be declared in the final publication (CSPI 2002; <u>FARM</u> 1997). Funding sources should be described in a way that allows an average reader to recognize potential conflicts of interest.

4.0 RESPONSIBILITIES OF EDITORS/JOURNAL STAFF/JOURNAL OWNERS

Journal editors can have a significant influence on the practice of addiction science, as well as treatment and prevention. Editors need to promote the highest standards of ethical practice in order to advance addiction science and to maintain the trust of the people their journals serve. The ethical responsibilities of editors include the ethical decision-making, the peer review process, advertising, conflict of interest, and how to deal with scientific misconduct.

4.1 Ethical Decision-making

4.1.1 Definition or Principle

Editors' decisions to accept or reject a paper for publication should be based only on the paper's importance, originality, and clarity, and the study's relevance to the remit of the journal (COPE 2001).

4.1.2 Guidelines

- 4.1.2.1 All original studies should be peer reviewed before publication, taking into full account possible bias due to related or conflicting interests (COPE 2001).
- 4.1.2.2 Studies that challenge previous work published in the journal should be given an especially sympathetic hearing (COPE 2001).
- 4.1.2.3 Studies reporting negative results should not be excluded (COPE 2001).
- 4.1.2.4 Editors must treat all submitted papers as confidential (COPE 2001).
- 4.1.2.5 When a published paper is subsequently found to contain major flaws, editors must accept responsibility for correcting the record prominently and promptly (COPE 2001).

4.2 Peer Review

4.2.1 Definition or Principle

Addiction journals should be committed to peer review, and both research reports and unsolicited scientific reviews should go through this process. Invited reviews and commentaries should also receive critical peer comment. Peer reviewers are external experts chosen by editors to provide written opinions, with the aim of improving the study or scholarly report. Working methods vary from journal to journal (COPE 2001). Reviewers are expected to behave in an ethical manner and the editor should consider breaches of the following guidelines as instances of misconduct no less serious than comparable actions by authors (DAD 2000).

4.2.2 Guidelines

- 4.2.2.1 Suggestions from authors as to who might act as reviewers are often useful, but editors should not be obligated to use those suggested (COPE 2001).
- 4.2.2.2 Editors must treat all submitted papers as confidential (COPE 2001). The duty of confidentiality in the assessment of a manuscript must be maintained by expert reviewers, and this extends to reviewers' colleagues who may be asked to give opinions on specific sections (COPE 2001). Referees should be told that their access to the papers on which they have been requested to comment is in strict confidence. Confidentiality should not be broken by pre-publication statements on the content of the submission. Manuscripts sent to reviewers should be returned to the editor or destroyed when the editorial process is complete (FARM 1997).
- 4.2.2.3 Reviewers and editors should not make any use of the data, arguments, or interpretations, unless they have the authors' permission (COPE 2001).
- 4.2.2.4 Reviewers should provide speedy, accurate, courteous, unbiased and justifiable reports (COPE 2001).
- 4.2.2.5 If reviewers suspect misconduct, they should write in confidence to the editor (COPE 2001).
- 4.2.2.6 To enhance the quality and efficacy of the peer review system, addiction journals should audit the quality of peer review on a continuous basis, and where possible, provide training to enhance the quality of peer review (FARM 1997). Journals should publish accurate descriptions of their peer review, selection, and appeals processes (COPE 2001). Journals should also provide regular audits of their acceptance rates and publication times

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(COPE 2001).

4.2.2.7 In refereeing journal supplements, an editorial note should be published to indicate whether or not the papers have been peer-reviewed (FARM 1997).

4.3 Advertising and reprints

4.3.1 Definition or Principle

Many scientific journals and meetings derive significant income from advertising. Reprints may also be lucrative. Financial considerations such as these have the potential to create a real or apparent conflict of interest.

4.3.2 Guidelines

- 4.3.2.1 Editorial decisions must not be influenced by advertising revenue or reprint potential; editorial and advertising administration must be clearly separated (COPE 2001).
- 4.3.2.2 Advertisements that mislead must be refused, and editors must be willing to publish criticisms of advertised products and services according to the same criteria used for material in the rest of the journal (COPE 2001).
- 4.3.2.3 Reprints should be published as they appear in the journal unless a correction is to be added (COPE 2001).

4.4 Conflict of Interest

4.4.1 Definition or Principle

'Conflict of interest' is defined as a situation in which professional, personal, or financial considerations could be seen by a fair-minded person as potentially in conflict with the reviewer's independence of judgement (FARM 1997). It has also been described as a situation or relationship which, when revealed later, would make a reasonable reader feel misled or deceived. Conflict of interest is not in itself wrongdoing (FARM 1997). A conflict may be personal, commercial, political, academic or financial. "Financial" interests may include employment, research funding, stock or share ownership, payment for lectures or travel, consultancies, and company support for staff (COPE 2001). The potential for conflict of interest in the addiction field is enhanced by any relationship or funding connected with the tobacco industry, the alcohol beverage industry, for-profit health care systems, private hospitals, the pharmaceutical industry, and "social aspect organizations" that receive their primary support from these sources.

There are three levels of conflict of interest: real, apparent, and potential. A real conflict of interest means that the editor, or the administrative unit with which the editor has an employment relationship, has a financial or other interest that could unduly influence the editor's position with respect to the subject matter being considered. An apparent conflict of interest exists when an interest would not necessarily influence the editor but could result in the editor's objectivity being questioned by others. A potential conflict of interest exists with an interest that any reasonable person could be uncertain whether or not it should be reported.

4.4.2 Guidelines

- 4.4.2.1 To protect the independence of the editorial process, the owner or sponsoring organization should be declared, and sources of support from the alcohol, tobacco, pharmaceutical or other relevant interests should be published in the journal (FARM 1997).
- 4.4.2.2 When a journal publishes journal supplements, sources of support for their production should be declared (FARM 1997).
- 4.4.2.3 Conflicts of interest, where relevant, must be declared to editors by researchers, authors, and reviewers (COPE 2001).
- 4.4.2.4 Editors should also disclose relevant conflicts of interest to their readers. Sometimes editors may need to withdraw from the review and selection process for the relevant submission (COPE 2001). If an editor considers he/she may be subject to Conflict of Interest, advice from a co-editor may be sought and a co-editor or guest editor should have full responsibility for editing the manuscript (DAD 2000).
- 4.4.2.5 Referees should be asked to declare to the editor if they have a conflict of interest in relation to the material which they are invited to review, and if in doubt they should consult the editor.
- 4.4.2.6 To further enhance the integrity of science, editors are urged to adopt a more complete disclosure policy (CSPI 2002). Such a policy should ask contributors to disclose to journal editors at least the following information:

Sources of funding for the study, review, or other item being published (CSPI 2002). Sources of funding for the submitted paper must be declared and should be published (<u>FARM</u> 1997).

Significant financial or other relations (e.g., consulting, speaker fees, corporate advisory committee memberships) of the author with companies, trade associations, unions, or groups (including civic associations and public interest groups) that may gain or lose financially from the results or conclusions in the study, review, editorial, or letter (CSPI 2002).

4.5 Dealing with Suspected Misconduct

4.5.1 Definition or Principle

"Scientific misconduct" includes fabrication, falsification, plagiarism, undeclared conflict of interest, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data (ORI 2000). According to the International Committee of Medical Journal Editors, editors have a responsibility to pursue possible scientific misconduct in manuscripts submitted to or published in their journals and to publish a retraction of any fraudulent paper published in their journals. However, editors are not responsible for conducting a full investigation or deciding whether scientific misconduct has occurred. Those responsibilities rest with the institution where the work was conducted or with the funding agency (ORI 2000). The general principle confirming misconduct is the intention to cause others to regard as true that which is not true (COPE 2001). The examination of misconduct must therefore focus not only on the particular act or omission, but also on the intention of the researcher or author involved (COPE 2001).

Deception may be by intention, by reckless disregard of possible consequences, or by negligence. It is implicit, therefore, that "best practice" requires complete honesty, with full disclosure. (COPE 2001)

In the following sections we present a set of guidelines that can be used by journal editors to investigate and respond to instances of suspected scientific misconduct. The accompanying flow chart describes the sequence of activities and decision points that should be followed before sanctions are imposed.

4.5.2 Guidelines

4.5.2.1 Investigating Misconduct. Because editors are expected to uphold and preserve the integrity of their journal, returning a manuscript that is suspect for scientific misconduct to its author is a disservice to the research community and may result in data being published that could adversely affect public health (ORI 2000). Editors should not simply reject papers that raise questions

of misconduct. They are ethically obliged to pursue the case. However, knowing how to investigate and respond to possible cases of misconduct is difficult (COPE 2001). Reviewers should be urged to report any suspicions noticed in manuscripts they are reviewing. Suspicious evidence includes but is not limited to: text that is plagiarized, data that are too perfect, and results that do not coincide with the methods used to conduct the research (ORI 2000).

Editors must take all allegations and suspicions of misconduct seriously, but they must recognize that they do not usually have either the legal legitimacy or the means to conduct investigations into serious cases (COPE 2001).

The editor must decide when to alert the employers of the accused author(s) (COPE 2001). If editors are presented with convincing evidence-perhaps by reviewers-of serious misconduct, they should immediately pass this on to the employers, notifying the author(s) that they are doing so (COPE 2001).

If accusations of serious misconduct are not accompanied by convincing evidence, then editors should confidentially seek expert advice (COPE 2001). If the experts raise serious questions about the research, then editors should notify the employers (COPE 2001). If the experts find no evidence of misconduct, the editorial processes should proceed in the normal way (COPE 2001).

Authors should be given the opportunity to respond to accusations of minor or serious misconduct (COPE 2001). A defined appeals process should be developed by each journal so that an independent "second opinion" can be obtained to make sure that the editor is following the journal's policy on scientific misconduct.

Editors may judge that it is not necessary to involve employers in less serious cases of misconduct, such as redundant publication, deception over authorship, or failure to declare conflict of interest. Sometimes the evidence may speak for itself, although it may be wise to appoint an independent expert. (COPE 2001)

Editors should remember that accusations of even minor misconduct may have serious implications for the author(s), and it may then be necessary to ask the employers to investigate (COPE 2001).

4.5.2.2 Sanctions. If convinced of wrongdoing, editors may wish to adopt some of the sanctions outlined below. Sanctions may be applied separately or combined. The following are ranked in approximate order of severity. (COPE 2001)

A letter of explanation (and education) to the authors, where there appears to be a genuine misunderstanding of principles. The editor must decide when to alert the employers of the accused author(s). (COPE 2001)

A letter of reprimand and warning as to future conduct (COPE 2001).

A formal letter to the relevant head of institution or funding body (COPE 2001).

Publication of a notice of redundant publication or plagiarism (COPE 2001).

An editorial giving full details of the misconduct (COPE 2001).

Refusal to accept future submissions from the individual, unit, or institution responsible for the misconduct, for a stated period (COPE 2001).

Formal withdrawal or retraction of the paper from the scientific literature, informing other editors and the indexing authorities (COPE 2001). If a retraction is accepted by the editor, it should be labeled as such, appear in a prominent section of the journal, be listed in the table of contents, and include in its heading the title and citation of the original journal article. (ORI 2000)

4.5.2.3 Policies. Each journal should have defined policies for response to attempted or actual instances of duplicate publication, plagiarism, or scientific fraud (FARM 1997). Experience in handling allegations of scientific misconduct indicates that there are several policies that editors could adopt that are likely to reduce the submission and publication of fraudulent manuscripts: reporting suspect manuscripts, co-author signatures, submission of data, and corrections/retractions (ORI 2000).

Reporting Suspect Manuscripts: As a specific step, editors should consider placing a notification in the journal's "Instructions to the Author" regarding reporting suspect manuscripts. This notification

would state that authors, by submitting a manuscript to the journal, will abide by the journal's policy and procedures for handling suspect manuscripts, including procedures for notifying the author's institution or funding agency. This notification should also state that authors agree to cooperate with an institution in investigating an allegation of scientific misconduct involving their manuscript or article. Research institutions should adopt similar policies which would direct institutional staff to cooperate with journals that are investigating suspect manuscripts or published papers. The Council of Biology Editors, a professional association of editors of many of the world's leading biomedical journals, has examined this issue and its Editorial Policy Board recently drafted language for the purpose of aiding journals with this task. The policy statement reads: "Should possible scientific misconduct or dishonesty in research submitted for review by the journal be suspected or alleged, the journal reserves the right to forward any submitted manuscript to the sponsoring or funding institution or other appropriate authority for investigation. The journal recognizes the responsibility to ensure that the question is appropriately pursued, but does not undertake the actual investigation or make determinations of misconduct" (Personal communication to ORI staff from chair, Editorial Policy Board, CBE, July 1998). (ORI 2000)

Co-author Signatures: Some misconduct cases have involved the publication of manuscripts without the knowledge or consent of all named co-authors. Requiring all co-authors to sign-off on the manuscript validates their accountability for the content of the manuscript and reduces the probability that a fraudulent manuscript will be submitted. (ORI 2000)

Submission of Data: Authors could be explicitly informed that their data may be requested during the review process or if questions arise following publication. (ORI 2000)

Corrections/Retractions: The policy should specify who may request a correction or retraction, the criteria for determining whether a correction or retraction would be published, and the form, content and location of the notice. Editors are urged to incorporate the standard for retractions suggested by the International Committee of Medical Journal Editors, in their policy on corrections and retractions: "The retraction, so labeled, should appear in a prominent section of the journal, be listed in the contents page, and include in its heading the title of the original

article. It should not simply be a letter to the editor. Ideally, the first author should be the same in the retraction as in the article, although under certain circumstances the editor may accept retractions by other responsible persons. The text of the retraction should explain why the article is being retracted and include a bibliographic reference to it" (International Committee of Medical Journal Editors, Uniform Requirements for Manuscripts Submitted to Biomedical Journals and Supplemental Statements, 1994, p.25). (ORI 2000)

Other assurances: To prevent or minimize concerns about ethical issues, editors should require that applicable authors give an assurance that ethical safeguards have been met (FARM 1997), that all authors have made substantive contributions to the preparation of a manuscript, and that the paper has not been published previously in whole or in part. In addition, the specific contribution of each author of a published paper (conception and design; analysis and interpretation of the data; drafting of the article; critical revision of the article for intellectual contents; final approval of the article; statistical expertise; administrative, technical or logistical support; and collection and assembly of data) should be declared to the journal editor (CSPI 2002).

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