



HANDBOOK FOR AUTHORS

AAOS PUBLICATIONS

PLEASE FAX OR MAIL FORMS TO: Sophie Tosta, Publications Department

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MEMORANDUM

From: The Publications Committee
American Academy of Orthopaedic Surgeons

Dear Author:

You were chosen because of your special expertise to contribute to one of the Academy's publications. The Academy's Publications Committee would like to thank you for your willingness to help carry out the Academy's central mission of providing high-quality, innovative educational material to its members and other professionals caring for the musculoskeletal system.

Whether you are in an academic setting or in private practice, we know that the demands on your time and your resources have never been greater. Therefore, the Academy wants to make the experience of contributing your material as easy and as trouble free as possible. This *Handbook* has been designed to provide you with all the information you'll need to produce and submit your contribution. The publication staff is eager to work with you to expedite your assignment.

If, after reading the *Handbook*, you have any questions, please direct them to Marilyn Fox, PhD, Director, Department of Publications, who will be happy to assist you, or answer any questions.

Thanks again, and we look forward to seeing the publication to which you are contributing.

Introduction

This *Handbook* has been prepared to aid you in the preparation and submission of your chapter or chapter section to be published by the American Academy of Orthopaedic Surgeons.

The *Handbook* contains important information and specific instructions that will help you prepare your manuscript and illustrations for submission. It is written for the experienced author and is not intended to serve as a general authority on manuscript submission.

All questions about the information contained in the *Handbook* should be directed to

Marilyn L. Fox, PhD, Director
Department of Publications
6300 North River Road
Rosemont, IL 60018
1-800-346-2267
fox@aaos.org

Preparing Your Manuscript

The following components make up the manuscript package that you will submit to the Academy:

Text

Illustrations

Assignment of rights form

Permissions forms if applicable

Author disclosure form

Patient releases if applicable

Contributor form

FDA disclosure statement

The Text of Your Manuscript

Length

For OKU and ICL Publications The following gives you a rough estimate: 3 typewritten pages per typeset page, given a typewritten page averaging 22 lines per page and 15 words per line. Consider that every piece of art is one quarter of a typeset page.

For Monographs The following gives you a rough estimate: 2.5 typewritten pages per typeset page, given a typewritten page averaging 22 lines per page and 15 words per line. Consider that every piece of art is one quarter of a typeset page.

For Symposium and Other Academy Publications The following gives you a rough estimate: 1.5 typewritten pages per typeset page, given a typewritten page averaging 22 lines per page and 15 words per line. Consider that every piece of art is one half of a typeset page.

Format

Paragraphs should be indented with a tab, rather than flush left.

Do not insert page breaks, except before the reference list and figure legends.

Please spell out all terms to be abbreviated at their first mention in the manuscript.

Significant terms of all headings should begin with capital letters.

Main headings should be centered.

Main subheadings should be typed at the left margin.

Tertiary headings should be typed in the text in bold face.

Title Page

The title page is an important tool for the AAOS staff. We use it to update our contributor information and to double check our records. The title page should include the following:

- the title of the paper
- each author's name as it will appear in the volume
- highest degree or degrees (MD, PhD)
- academic/professional title that the author wishes to have listed on the contributors' page of the book
- institution name or practice setting
- mailing address
- telephone number
- fax number
- the name of the contact in your office who will answer questions about the manuscript.

Legends

A figure legend must be provided for each piece of art submitted. Please make sure the legend explains any arrows, letters, or other indicators that appear in the art. A complete list of all legends should appear on a separate page following the reference list.

Credit lines must be included for any previously published art.

Previously published art must include the following:

- completed permission request form
- names of first six authors
- title of article/chapter
- editor of book/journal if applicable
- city, state, and name of publisher
- year of publication
- volume number
- inclusive page numbers

figure number and page number as it appears in the original publication.

If you intend to reproduce an illustration from another source, photocopy the title page of the book (if applicable), and the first page of the chapter or article and illustration as it was published in its original form.

Tables

Each table should begin on a separate page and should follow the figure legends. Each table should have clearly marked headings, and abbreviations should be

spelled out and explained at the end of the table. If the table has been previously published, please provide a complete credit line at the end of the table listing the following:

names of first six authors

title of article/chapter

editor of book/journal if applicable

city, state, and name of publisher

year of publication

volume number

inclusive page numbers

figure number and page number as it appears in the original publication.

If the table is reproduced from another source, please provide a photocopy of both the title page of the book (if applicable), the first page of the chapter or article, and table as it appeared in its original form.

References

Academy staff will ensure that all references are correctly formatted, but it is **the author's responsibility** to ensure that all references submitted contain **complete** and **accurate** information.

For OKU and Basic Science Publications References are not called out in text; instead they appear unnumbered, arranged alphabetically by section of the manuscript. This bibliographic list should be selectively annotated. The annotation should follow the entry and should be written in full sentences. All references should be to recent publications.

Example reference entries:

Fowles JV, Slimane N, Kassab, MT: Elbow dislocation with avulsion of the medial humeral epicondyle. *J Bone Joint Surg Br* 1990;72:102-104.

Retrospective comparison of surgical and nonsurgical management of medial epicondylar fractures followed for at least 18 months showed an increased incidence of flexion contractures in the group receiving surgical treatment.

For Symposium, ICLs, Monographs, and Other Academy Publications

References should be numbered in the order in which they are mentioned in the text. **Do not alphabetize references.** The reference list should be typed or printed double-spaced and should follow directly after the text. References should be listed according to the style set forth in the *AMA Manual for Authors and Editors*. If you do not have this manual, the following examples can serve as a guide.

Example references:

1. Jones J: Growth plate abnormalities. *J Bone Joint Surg Am* 1982;64:691-703.
2. Marks W: Fractures of the lower extremities, in Smith P (ed): *Fundamentals of Orthopaedics*, ed 3. New York, NY, Academic Press, 1986, pp 197-228.

Reference to Journals A complete journal reference includes author, title of article, title of journal (abbreviated according to *Index Medicus* listing), year, volume number, issue number (only if pagination is not consecutive throughout the year's issues), and inclusive pages.

Reference to Books A complete reference to a book includes author; title of chapter or section; editor or translator, or both, if listed; title of book and subtitle, if any; number of edition after the first; place of publication including city, state, and country (if other than U.S.A.); name of publisher; year of publication; volume number, if any; and inclusive page numbers.

Reference to Unpublished Material References are included in our publications both to inform readers of the sources of information and to enable readers to find and read books and journal articles that are of special interest to them. Some references (to oral presentations at scientific meetings, poster presentations, unpublished data, and papers submitted for publication but not yet accepted) are not available for reading and, hence, are less useful to our readers. For this reason, references should be to published material.

You may include unpublished data or personal communications, however, these should be listed in the body of the text, not in the reference list, and should include the full name and degree of the source of the information, as well as the year, city, and state.

Pictorial Material

The rights to original illustrations, as part of the manuscript, must be assigned to the Academy as publisher. Unpublished photographs of patients, if they portray any part of the body that might identify the patient, can be used only if the patient or the patient's guardian(s) consent to their use. Permission must be sought by the Academy to include previously published illustrations, such as photographs, line drawings, charts, graphs, and radiographs, submitted by the authors as part of their manuscripts. **Because such permissions are becoming**

more difficult and often quite expensive to obtain, the Academy requests that authors submit original illustrations whenever possible.

Illustration Submission Guidelines

Illustrative Materials

Illustrative materials include black and white halftones, or color photographs and transparencies; line drawings; radiographs; CT scans, and MRI scans. We accept high quality photographic prints of illustrative materials, sized anywhere from 8" x 10" to 3" x 5", or digital images, providing the digital files are furnished to the specifications outlined below. See "Digital File Submission."

Preparation of Materials

Authors should submit original illustrative materials in an envelope with the original manuscript and a disk. Whether you are submitting a high quality photographic print of an image, or a digital file of one, you should submit a laser print out of the image as well. If you do not have the originals, try to obtain them before you submit the manuscript. **If the originals are not available to you, we will not be able to obtain them for you.**

Review the illustrative materials before submission to verify that the images are sharp and clear. We reproduce all illustrative materials exactly as shown on the originals submitted. Although we can improve the quality of some images through scanning technology, if the image is blurred, or washed out, we will not be able to correct that.

All illustrative materials are reviewed in-house to ensure a quality print reproduction. You will be contacted about any illustrations that do not meet our submission standards for the print production process.

When the edited manuscript is sent to you for review, we will include proofs of the illustrations with the edited manuscript for your approval. If the illustrations do not meet our quality standards, we will ask you to select ones of better quality and send those to us when you return the edited manuscript.

Once the illustrations are accepted for publication, they become the property of the AAOS and will be archived with the book.

Line Drawings and Graphs Most line drawings and graphs are used as submitted. However, if the line drawing or graph will not reproduce well, or if the labels are unreadable, we may have it redrawn. **Please be sure that all line drawings and graphs fit with the copy in the manuscript; if they do not, we will ask you to modify them so they can be redrawn.**

Be sure to create all labels for charts and figures in easy-to-read lettering. Any abbreviations that are used in charts and figures should be identified in the figure legend. If a Mac or PC drawing program was used to create the chart or graph, please submit the original application file, eg, Illustrator, Corel Draw, etc, along with a laser print of it. For more information on submitting illustrative materials electronically, see “Digital File Submission” below.

Radiographs, CT, MRI Make photographic prints of original radiographs, tomograms, or MR images. Do NOT submit originals.

Photographs of Patients If the patient or any other person is identifiable, the art will be cropped and the faces will be obscured unless permission to use the photograph is given by the patient shown in the photograph, or by the patient’s guardian if a minor is shown.

Photomicrographs and Electron Photomicrographs Histologic specimens will be reproduced in black and white. Where appropriate, magnifications should be given in the legends.

Labeling

Print or type the following information on a label and attach it to the back of each illustration:

Your Name

Manuscript title (abbreviation okay)

An arrow indicating “top” of the illustration

Figure number to show order of appearance in text.

Please create all labels for charts and figures in easy-to-read typed or hand lettering. Identify any abbreviations used in charts and figures in the figure legend.

Cropping

Use crop marks to crop out any unnecessary parts of the illustration. **Do not write directly on the back or front of the illustrations.** This will damage the illustration and we will not be able to use it for publication. Crop marks can be

added in the margin of the illustration or on a photocopy of the image. Any arrows or other locator should be marked on the photocopy, not the illustration.

Digital File Submission

We accept most PC and Macintosh graphics programs such as Photoshop, Illustrator, Freehand, and Corel Draw. Files saved as EPS or TIFF files are acceptable providing they were scanned at the correct resolution for printing. If you submit digital images, please be sure to submit a laser printout of the image with the labeling information described above for each illustration on the disk. Label the disk with your name, abbreviated title of the manuscript and the number of images on the disk.

Image resolution The AAOS accepts digital files of illustrations providing they are submitted according to our specifications outlined below. Images displayed on web sites are compressed JPEG files, scanned at a resolution of 72 ppi (pixels per inch), or dpi (dots per inch). If you do send us a JPEG image, we will request that you send us an original photographic print that we can scan at a higher resolution. The print production process requires that images and line art be scanned at the following resolutions:

- ❑ 300 ppi for halftones (black and white photographs or color)
- ❑ 1200 ppi for line art
- ❑ 600 ppi for combination halftones (photograph with lettering), or just lettering

Images captured with a digital camera have an acceptable resolution at the time they are captured digitally and can be submitted as is. If your illustration was created in a CAD/CAM or 3-D imaging program, we will not be able to use it so send a photographic print of it.

Accepted Media We accept 3.5 Iomega ZIP disks formatted for Mac or PC, CD Rom or 3.5" diskettes formatted for Mac or PC

Compression software We accept PKZIP or WINZIP (Dos or Windows), Stuffit for Macintosh, or any self-extracting software.

Your Intellectual Property Rights and Responsibilities

The following information has been provided so that you understand your rights and responsibilities as an author of material to be published by the Academy. Please take a few moments to review this information and the definitions that accompany it.

According to U.S. copyright laws, the material you create, including any illustrations, is your intellectual property by virtue of the fact that you created it. **The only exception is material you may create as an employee, which is the property of your employer.**

As an author, you own the copyright in your material. In return for making this material ready for publication, a publisher asks the author to turn over, or **assign**, this copyright to the publisher. This means that the ownership of the material is transferred from the author to the publisher. This transfer is a condition of publication that authors have agreed to for many years.

Some authors have recently asked the question: “Why should I give my material to a publisher?” The answer to this question involves knowing what a publisher does. First of all, the publisher has the financial means and the staff to refine the material, to have it reviewed by an editor and/or peer reviewed, to distribute it widely, and to promote its existence. This enhancement and widespread dissemination can rarely be done by the author, and, therefore, the publisher performs an important service by promoting the expertise of the author throughout the world and making available an important contribution to the orthopaedic literature. Publication in medical texts and scientific journals also enables authors to gain peer recognition, which may lead to academic advancement and/or to the dissemination of the author’s ideas, techniques, and overall expertise.

There are some very compelling reasons for a publisher, in this case the Academy, to hold the copyright in the material you submit. The Academy registers its copyrights with the U.S. Copyright Office. If a case of plagiarism or other unwarranted use of the material is discovered, the Academy can then seek punitive damages against the offending party.

Owning the copyright to the material also allows the publisher, who has a significant financial investment in the publication, to monitor the requested republication of the material elsewhere. An author who writes a chapter or an article for the Academy may want to publish all or part of it in a textbook or

journal published by another publisher. Or another individual may want to republish a part of it, usually illustrations, in another book. By owning the copyright to the original material, the Academy as publisher can review these requests and determine whether they are appropriate. The Academy receives hundreds of these requests each year, and has staff dedicated to process them. **The Academy has never refused the originating author's request to republish the material elsewhere**, but the Academy has disallowed requests from others who want to use the material for an inappropriate purpose, such as self-promotion, or to associate their name with the Academy's.

Without the ability to monitor the re-use of its material, a publisher could be faced with a situation in which it had spent thousands of dollars to publish a book only to learn that much of the material had been already published or subsequently published in a competing text.

In the case of the Academy, which uses all of its net revenues from publications to support other important educational projects and to help keep membership dues as low as possible, this situation could have a deleterious effect if it compromised the salability of the text.

Being able to monitor the re-use of this material also helps the publisher to protect the reader from buying books that have identical information from the same author. This is an example of **duplicative publication**, which is defined on page 13. Owning the copyrights to the material it publishes also enables the Academy to build a repository of intellectual property that can be used in future works published by the Academy, including subsequent editions, CD-ROM versions, and translations.

For all of these reasons, The Academy's Council on Education in 1998 reaffirmed the Academy policy of having authors who contribute to enduring materials such as books, journals, and CD-ROMs, assign their copyrights to the Academy as a condition of being published. These rights are assigned by means of a form that accompanies your invitation letter.

In order to ensure that each author understands the assignment of rights form included in this *Handbook*, as well as other terms used in discussion of intellectual property rights, the following definitions have been provided. If you have additional questions, please contact Marilyn Fox at the address listed on page 3.

Definition of Publishing Terms

1. Author An individual who creates an original work. As stated in the “Uniform Requirements for Manuscripts Submitted to Biomedical Journals,”¹

Each author should have participated sufficiently in the work to take public responsibility for the content.

To take responsibility, an author must be able to defend the content and conclusions of the article if publicly challenged. Sufficient participation means that substantial contributions have been made in *each* of the following areas:

1. conception and design **or** analysis and interpretation of the data; and
2. drafting the manuscript **or** revising it critically for important intellectual content; and
3. approving the version of the manuscript to be published.

According to the *American Medical Association Manual of Style*,² a “**substantial contribution** is an important intellectual contribution, without which the work could not have been completed or the manuscript could not have been written or submitted for publication.”

2. Assignment of rights/assigning your rights A complete transfer of ownership from the creator or owner of the work to another person or entity. This transfer assumes and requires that the creator is the sole owner of the entire work being submitted. If you are the only author of a chapter and six illustrations, you would assign your rights in the entire work to the Academy. If you are the author of a section of a chapter, you would assign your rights to that section.

The assignment also assumes that you have not received the rights for the work from someone else for a limited use or time, have not transferred any rights relating to the work already, and are willing to seek permission from the new owner (the publisher) to use the work in the future for any purpose.

For authors of AAOS publications, this is the required method of transfer for material that will be used for educational purposes and that may be used

repeatedly (e.g., different editions of a text) and for different purposes (e.g., for multimedia and textbook publications). **See the sample form, page 18.**

3. Copyright According to the U.S. Copyright Act of 1976,³ which became effective January 1, 1978, “the owner of copyright . . . has the exclusive right to do and to authorize any of the following:

- to reproduce the copyrighted work in copies or phonorecords;
- to prepare derivative works based on the copyrighted work;
- to distribute copies or phonorecords of the copyrighted work to the public by sale or other transfer of ownership, or by rental, lease, or lending. . . . “

4. Copyright Infringement According to the U.S. Copyright Act of 1976, “Anyone who violates any of the exclusive rights of the copyright owner . . . is an infringer of the copyright.” (90stat.2584) According to the *American Medical Association Manual of Style*, “to copy or reproduce an entire work without authorization from the copyright owner constitutes copyright infringement.”² In most publication agreements and in assignment of rights transfers of ownership, the publisher or end-user agrees to pursue any known, unauthorized use or copying of the material on behalf of the author. Thus, when an author assigns copyright to the Academy, it agrees to pursue copyright infringement, including assuming the financial burden for doing so.

5. Duplicative Publishing The simultaneous or subsequent publication of the same material by the same author(s) in two or more different places or media (print, CD-ROM). Duplicative publication occurs when an author submits the same or virtually the same manuscript to two or more publishers. This practice is not necessarily unethical, but “failure to disclose the existence of duplicate articles, manuscripts, or other material is unethical and may represent a violation of copyright law.”²

Duplicative publishing sometimes occurs because an author does not understand that once the rights in a manuscript have been assigned to one publisher, the manuscript cannot be re-submitted, without first requesting permission, to another publisher. In duplicative publication, unless the author informs the publishers, neither publisher knows the manuscript has been published by the other. Legally, the manuscript belongs to the first publisher, and the author or the second publisher must request permission for its use from the first publisher.

Some authors believe that they have the right to submit their work to as many publishers as they choose because they created the material. However, once an author’s rights have been assigned, they belong to the publisher. Many

publishers, including the Academy, grant permission for the re-use of material, but an author must receive this permission before submitting the material to another publisher.

6. Indemnification The owner of a copyright (author or other entity) who transfers ownership to the publisher must promise that certain things are true about the material. See the definition of **warranty** below. The original copyright owner agrees to protect the publisher against any losses if the material is found to violate any of these “promises.”

Indemnification gives the “teeth” to the warranties. If an author does not diligently confirm or tell the truth about the originality or ownership of the material, and the publisher gets sued as a result of these false assertions, then the author/owner agrees to pay the litigation costs and settlement or judgment expenses. Why is this necessary? Because the publisher is not involved in the development and creation process for the material, there is no way the publisher can know if an author is telling the truth about the material submitted. It could be plagiarized (see definition below) or it could have been previously published, or it could contain injurious statements. Because the publisher accepts the word of the author, the author must tell the truth. **If you as an author are ever unsure about the originality or ownership of any part of your material, please contact Marilyn Fox, who will help you determine its status.**

7. Paraphrasing According to the *American Heritage Dictionary*, paraphrasing is “A restatement of a text or passage in another form or other words, often to clarify meaning.”⁴ Paraphrasing without giving attribution to the original source is a form of **plagiarism** and can be avoided if the author remembers to cite the source from which the ideas or facts have been taken.

8. Plagiarism According to the *AMA Manual of Style*, plagiarism is the act of presenting as one’s own, the “ideas, language, data, graphics, or even scientific protocols created by someone else. Plagiarism of published work may violate copyright law . . . as well as standards of honesty and collegial trust and may be subject to penalties imposed by a court should the holders of the copyright bring suit.”² There are different kinds of plagiarism but the common element is the misrepresentation of someone else’s work as one’s own. Such failure to acknowledge a source may result from careless notetaking or ignorance of the “canons of notetaking and scholarship.”²

9. Warranty A warranty is a promise that certain things are true—in the case of an assignment or license of creative work, the owner, usually the author, may

promise that the material is not plagiarized (see definition above), does not falsely demean and injure the reputation of another (libel) or violate personal (like privacy) or property (like trademark or patent ownership) rights, is original and hasn't been previously published, and isn't the subject of any current litigation or claims.

Warranties are contained in virtually all publishing agreements, assignments of rights forms and license forms. They protect the ultimate end-user (the publisher) against claims from third parties that their rights have been violated by the content of the material. Publishers need this protection because they have no way of determining whether the material being submitted is free of these problems.

10. Work Made for Hire This work is created by an individual who is paid specifically to create the work, which may be an illustration or a magazine article, or a photograph, or any creative piece. There are two categories for these works. In the first, the work is created by an employee, and the copyright is held by the employer; in the second, the work is created by an independent contractor, and **both parties must sign an agreement before the work begins** stating that the work is a work made for hire, and that the copyright belongs to the one who is paying to have the work done.

This concept is important in intellectual property and has practical application for authors who have illustrations or other art commissioned for submission with their manuscripts. An author must make sure he or she has a signed agreement with the illustrator **unless** the illustrator is an employee of the author.

If the artist will not sign over the right, then the author may be able to obtain a license for one-time use. As an author submitting illustrations to the Academy, if you warrant that the illustrations are yours, then either one of the above conditions must be met, or you will be submitting something as yours, the illustrations, that legally belong to someone else, the illustrator or the illustrator's employer.

Reference List

1. International Committee of Biomedical Journal Editors: Uniform requirements for manuscripts submitted to biomedical journals." *JAMA*. 1997;227:927-934.
2. Ethical and Legal Considerations, in *American Medical Association Manual of Style*, ed 9. Baltimore, MD, Williams and Wilkins, 1997, Chapter 3, pp 87-172. ©American Medical Association, 1997.
3. Public Law 94-553. 94th Congress, U.S. Government Printing Office, 1983, p. 90stat.2456.
4. *The American Heritage Dictionary of the English Language*. Boston, MA, Houghton-Mifflin, 1981, p. 951.

SAMPLE ASSIGNMENT OF RIGHTS

I am a contributor to an educational project of the American Academy of Orthopaedic Surgeons ("Academy"), located at 6300 N. River Road, Rosemont, Illinois, 60018-4262. I have received no compensation from the Academy for my contributions. For purposes of this Assignment of Rights Agreement, I understand that the Academy includes not only the Academy as a corporation, but also any affiliated organizations and any of the Academy's employees, agents, licensees and assignees.

I have assisted or am assisting in the creation of a book, manual, article, survey, electronic media product, research instrument or other product (the "Work" *) that is being developed by the Academy. I agree that the Work may be published or otherwise used by the Academy to further the Academy's educational endeavors.

By signing this Agreement, I understand that I am giving the Academy whatever ownership interests I have or may have in the copyright of the Work, including the rights to any illustrations or photos I have prepared, submitted or developed. Specifically, by signing this Agreement, I understand that:

1. I am giving the Academy the entire worldwide right, title, interest, ownership and all subsidiary rights I have or may have in the Work; and
2. I have retained no personal or proprietary rights in the Work; and
3. I have given the Academy any future rights to commence any legal action or to recover damages and other relief resulting from infringement of the copyright in the Work.

I have no knowledge of any lawsuits, claims or demands relating to the Work nor have I conveyed or assigned any claim, potential claims or any part of the Work to any person or entity other than the Academy.

I am the sole author of this material and the owner of all rights granted in this Agreement. My contribution to the Work is original and has not been previously published. I warrant to the Academy that the Work does not violate or infringe any law or any right, including privacy and copyright, and it contains nothing libelous, injurious, or untrue. If a claim is filed against the Academy that my portion of the Work is not original, has been published elsewhere or infringes upon the rights of another person or entity, I agree to be legally responsible and to cover any judgments, claims, settlements and costs that arise as a result of this claim.

I understand that the Academy may edit my portion of the Work for publication or other uses. If the Academy accepts this Assignment of Rights, I understand that the Academy does not bind itself to use my portion of the Work in its original form or in its entirety. I also understand that if the Academy's alteration or removal of a section of my material causes the material to be libelous, injurious or untrue, I will not be legally responsible.

I am making this Assignment of Rights as a voluntary contribution to the Academy. Consequently, I am releasing the Academy from any responsibility to pay money or otherwise provide any form of compensation for its use of the Work.

Being of sound mind and body, I have full power and authority to enter into this Assignment of Rights.

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Date: _____ By: _____ (signature)
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The Permissions Process

As publisher, the American Academy of Orthopaedic Surgeons is responsible for protecting its own copyrighted material (art, tables, text), as well as for acknowledging in its publications the copyrighted material of others. The Academy will work closely with you to ensure that the material you submit is protected by copyright. Therefore, **please** provide the Academy with complete bibliographic information about any previously published material that you are submitting to us. This can be accomplished by:

1. **Completing the permission form.** Please complete the attached permission request form or, if the material has not been previously published, complete the original artwork form; and by
2. **Providing complete credit lines.** Please include complete credit lines on all illustration legends and tables reproduced or adapted from another source and submitted as part of the manuscript. Complete credit lines include the following:
 - names of all authors
 - title of article/chapter
 - editor of book/journal if applicable
 - city, state, and name of publisher
 - year of publication
 - volume number
 - inclusive page numbers
 - figure number and page number as it appears in the original publication.
3. **Providing support materials.** Please include a copy of the **title page** and the illustration or table as it was published in its original form. We require these because the publishers will request them from us when we apply for permission.

Example credit line: (Reproduced with permission from Jones J: Growth plate abnormalities. *J Bone Joint Surg Am* 1982;64:691-703.)

SAMPLE PERMISSION REQUEST FORM

Please complete a separate permissions request form for each figure/table/outline that requires permission. Photocopy this form if necessary. Also include a photocopy of the title page and illustration from its source.

Please complete an Original Artwork form for all illustrations/tables/outlines that do not require permission.

I, _____, acknowledge that the following illustration [] or portion of text [] has been used in my chapter or chapter section entitled

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Author(s) _____

Title of Article or Chapter _____

Title of Book or Journal _____

Name of Editor/s (if book) _____

Year Published _____

Publisher _____

Volume Number _____

Issue Number (if needed) _____

Inclusive Page Numbers _____

Original Page and Figure Numbers _____

I understand that the Academy, as publisher, will seek permission from the above-listed copyright holder. If I need a copy of the granted permissions, I will contact the Academy's permissions department.

SAMPLE ORIGINAL ARTWORK FORM

Please complete this form for all artwork that is original (has never been published elsewhere) to your manuscript. (NOTE: It is not necessary to fill out a separate Original Artwork form for each piece of artwork).

Figure(s):

Table(s):

Outline(s):

I, _____, acknowledge that these illustrations/tables/outlines have been used in my manuscript entitled

to be published by the American Academy of Orthopaedic Surgeons. I own all the rights to this material, and it has not been previously published elsewhere.

Signature of Author: _____

Date: _____

**AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
SAMPLE PHOTOGRAPH CONSENT FORM**

Please complete this form or a comparable one supplied by your institution for any photograph of a patient in which the patient is identifiable. Please be sure that the patient's name or initials and any identifying case number have been removed or can be cropped.

I, _____ [print name], the undersigned, hereby grant the American Academy of Orthopaedic Surgeons (the Academy) permission to use the photographs of me that were furnished by _____ [author name] for inclusion in _____ [title of book].

Further, I relinquish and give to them all rights, title, and interest I may have in the photographs.

The Academy agrees to use the photographs for educational purposes only.

Signature: _____

Date: _____

Name of parent or legal guardian if patient is under 18:

Signature: _____

Contributor's Page

Accurate completion of this form is important. The Academy staff will use this form to enter your name and affiliation into the front matter of the volume. We will enter your affiliation as you submit it: therefore, please be accurate.

We are limited to one affiliation per contributor. You can submit your academic or professional affiliation.

If we have not received your Contributors' Form with your manuscript we will assume that you wish us only to list your full name, city, and state.

SAMPLE CONTRIBUTOR'S PAGE FORM

Please fill out the information below for the book's Contributors' Page. Because it is the Academy's policy to list only **one** affiliation for each contributor, please list your affiliation as it should appear in this publication. Thank you.

Please print legibly or type the following information.

Name, Degree(s) _____

Title _____

Department or Practice _____

Institution _____

City, State _____

Signed: _____

Date: _____

Author Disclosure Statement

Disclosure Requirement

All individuals whose names appear as authors of materials to be published by the American Academy of Orthopaedic Surgeons must complete the Disclosure Statement below. Please read each of the two statements and check the space opposite the statement that applies to you. If receipt of something of value is disclosed, a statement to that effect will appear in conjunction with your chapter.

The American Academy of Orthopaedic Surgeons does not view the existence of disclosed interests or commitments as necessarily implying bias or decreasing the value of your work; however, any material lacking a signed disclosure statement from all authors whose names are to appear on the title page cannot be published. Failure to complete this form may, therefore, prevent the Academy's publication of your work.

DISCLOSURE STATEMENT:

With reference to the material entitled

I, _____
or the department(s) with which I am affiliated.

Have received something of value* from a commercial or other party related directly or indirectly to the subject of my chapter.

Please indicate type of value:

Research or institutional support from a commercial source or sources

Income or nonincome support, commercially derived honoraria, retainers, or other non-research-related funding

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Have received nothing of value* from a commercial or other party related directly or indirectly to the subject of my chapter.

*Any item, payment, service, or exchange valued at \$500.00 or more.

SIGNATURE _____ DATE _____

FDA Clearance Status and AAOS Policy

In September 1997, the Academy's Board of Directors approved a policy related to the FDA classification of devices and pharmaceuticals. In this section of the Handbook, you will find information pertaining to this new Academy policy and your responsibilities for upholding it. This section contains:

A letter from Dr. Douglas Jackson, Academy President 1997-98

The AAOS policy

A sheet highlighting your responsibilities as an author



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November 1997

TO: Faculty Members, Program Developers and Editors

FROM: Douglas W. Jackson, MD
President *Douglas W. Jackson*

SUBJECT: New Academy CME Policy on FDA Classification of Medical Devices and Pharmaceuticals

A new CME policy was adopted by the Academy Board of Directors in September 1997. It is the product of a year of deliberations by a Task Force of the Council on Education, and has received substantial legal input as well. The intent of the new policy is to make the Academy's educational offerings more useful to practicing physicians, and ultimately to benefit patient care. I have attached the full policy for your convenience. It is effective immediately.

The policy, in brief, contains the following basic principles:

- The presenter/author should know and state the FDA clearance status of any device or medication for the uses discussed.
- The presenter/author should note in particular whenever he or she discusses a use for which the device or medication has not been cleared by the FDA. This is considered an "off-label" use. It is important to remember that practicing physicians may use devices or medications "off label" if, in their judgment, such use is medically indicated to treat a patient's condition.
- Fairness and impartiality are the basic tenets of the Academy's education programs and generic rather than trade names should be used unless there is no alternative; a presentation focusing on one device or medication should also include discussion of similar products.
- The patient's best interest is the basis of physician decision-making.

I continue to appreciate your volunteer efforts on behalf of the Academy's educational programs and am confident that you will do your part to implement this new CME policy.

attach.

Excerpted from
FDA Classification of Medical Devices and Pharmaceuticals

It is the orthopaedic surgeon's responsibility to know the FDA clearance status of any medical device or pharmaceutical used in the treatment of patients. These uses may be described and taught in presentations made during Academy Continuing Medical Education (CME) events and in "enduring materials" (e.g. publications, videos, electronic media products). The purpose of this policy is to guide Academy chairmen and faculty members in CME events as well as authors and presenters of enduring materials in presenting information about the FDA clearance status of medical devices or pharmaceuticals for the uses described in their presentations and materials.

The Food, Drug and Cosmetic Act of 1938, as amended, establishes the basic legal framework controlling the activities of producers of food, drugs, cosmetics and medical devices. The most comprehensive set of amendments to this Act occurred in 1976. The 1976 Medical Device Amendments ("Amendments") created a complex system for regulating the development, introduction, and marketing of medical devices. These Amendments require the FDA to classify or categorize all medical devices according to their safety and effectiveness. These classifications may vary for a medical devices based upon their "intended use." The Amendments create three classes of devices:

Class I Includes uses for those devices presenting little risk to the public and which are generally recognized as being both safe and effective. Neither quality and performance standards nor FDA pre-marketing regulatory approval are necessary. This classification is subject to minimal FDA oversight. This oversight includes only those general regulatory controls available to the FDA to assure safety and effectiveness (e.g., registration, listing and compliance with safety controls).
Examples of Class I devices include cast materials, crutches and wheelchairs.

Class II Includes uses for those devices determined by the FDA to offer some additional risk to the public above Class I devices, for which the above

mentioned regulatory controls are not sufficient to assure safety and effectiveness, but for which sufficient information exists to develop performance standards. Device uses falling into this category must comply with the general requirements for Class I devices and, in addition, any other performance standards developed by the FDA. Examples of Class II devices include intramedullary nails, bone screws and plates when used for long bone fractures, and cemented hip replacements.

Class III Includes uses for those devices for which general regulatory controls are not sufficient to assure safety and effectiveness, which may offer a substantial risk to the public and for which there is not sufficient information to establish a performance standard. Class III devices are generally considered to be “new” medical device uses requiring a showing of safety and effectiveness through a pre-market approval prior to labeling for the intended use. Class III devices may also be approved for certain intended uses if determined to be “substantially equivalent” to a pre-Amendment device.

Examples of Class III devices currently (9/97) include ligament replacements and bone substitutes and the use of bone screws in the pedicle.

Enduring Educational Materials

1. FDA Clearance Status Included in Discussion of Devices or Pharmaceuticals in Enduring Materials

If a medical device or pharmaceutical, not cleared by the FDA or cleared by the FDA for a specific use only, is discussed or described in an Academy enduring educational program or publication, the author or presenter is responsible for including the FDA clearance status of the product as it relates to the uses described in the materials at the time of publication. This information should be included in the enduring materials with the discussion or description of the product, and not in an appendix.

2. Discussion of Investigational Uses of Devices or Pharmaceuticals in Enduring Materials

Medical devices or pharmaceuticals not cleared by the FDA for an intended uses are required by law to be labeled “for investigational use” if there is an existing IDE application for study of the intended use. When these investigational intended uses are discussed or described during an Academy enduring educational program or publication, the author or presenter shall disclose that the device or pharmaceutical is classified by the FDA as investigational with respect to the intended use. Results of scientific studies known to the author or

presenter relating to the described use should be discussed if doing so will not adversely affect the study or violate some other regulatory requirement.

3. Discussion of “Off Label” Uses of Devices or Pharmaceuticals in Enduring Materials

Some medical devices or pharmaceuticals not cleared by the FDA or cleared by the FDA for a specific use only may be used “off-label” (i.e., a use not described on the product’s label) if, in the judgment of the treating physician, such use is medically indicated to treat a patient’s condition. “Off label” uses of a device or pharmaceutical may be described in Academy enduring educational programs or publications so long as the lack of FDA clearance for such uses is also disclosed. Results from scientific studies known to the author or presenter relating to the described intended use should be discussed if so doing will not adversely affect the study or violate some other regulatory requirement.

4. Use of Generic or Trade Names by Authors or Presenters

It is important that Academy courses provide a balanced view of therapeutic options for the treatment of musculoskeletal patients. The use by authors or presenters of generic names to describe a device or pharmaceutical creates a sense of impartiality and is strongly encouraged. When a trade name is used in an enduring educational program or publication, the author or presenter should, when possible, list or cite other similar devices or pharmaceuticals from other companies.

Carrying out the AAOS Policy

What you as the author must do:

1. Include the clearance status of all class II and Class III devices, as that status relates to the use being described in your paper.
2. Reveal the investigational status of all devices or pharmaceuticals that have an existing IDE (investigational device exemption) application for the use being discussed. Also, reveal any knowledge of the results of investigations, provided it will not adversely affect the study or violate regulatory requirements.
3. Disclose the lack of FDA clearance for the “off-label” use of any drug or device when you are discussing its off-label use. Also, reveal any knowledge of the results of investigations of the off label use, provided it will not adversely affect the study or violate regulatory requirements.

4. Use generic names instead of trade names unless impossible, and when using trade names, try to include other trade names for the same product.

How to find the FDA clearance status (classification)

1. Look at the product package labeling information accompanying the product.
2. Call the FDA's toll free number: 800-638-2041.
3. Contact a sales representative or the legal counsel of the manufacturer.

What drugs and devices can be discussed without mentioning the FDA class?

Class I devices being used for specific purposes

What discussion of drugs and devices must be accompanied by reference to the FDA clearance status?

Class II and Class III drugs and devices

All drugs and devices being used off label

Does every mention of a Class II or Class III or off-label use have to be accompanied by a citation of the class or status?

Any reference to a personal or recommended use or any evaluation of the drug or device must include the class citation. Any passing reference, such as the following, may omit the citation: "Non-cemented implants were first used in 1979."

SAMPLE FDA DISCLOSURE FORM

I _____ have read the Academy's CME Policy on FDA Classification of Medical Devices and Pharmaceuticals pertaining to enduring materials and have, to the best of my knowledge, listed the appropriate FDA classification for all medical devices and pharmaceuticals mentioned in my chapter or chapter section.

SIGNATURE _____ DATE _____

Submitting The Manuscript

The manuscript, including references and figure legends, should be typed using a word processing program.

The manuscript should be double-spaced and have generous margins (1 inch) at the top, bottom, and on the sides.

The manuscript should be copied to a 3.5" disk labeled with the author's name, article title, and the type of system and software used to produce it.

The disk should be sent to the Academy with the manuscript, where the staff will format it to accommodate Academy style.

The Academy word processing system is Microsoft Word 6.0; however, we can accept disks in most Mac and PC formats. If you have any questions regarding how your manuscript should be saved and sent, please call your contact listed on the front of this handbook.

The author should submit:

- one hard copy of the manuscript (including any tables),
- a word processor diskette,
- two copies of each illustration
- all applicable forms

Please send your manuscript to:

THE AUTHOR SHOULD KEEP A COPY OF THE ORIGINAL MANUSCRIPT (including illustrations and tables).