

MANUSCRIPT CRITERIA AND INFORMATION

The *Archives of Dermatology* is an international, peer-reviewed, dermatologic journal, with distribution to readers in more than 95 countries.

Manuscript Submission.—All manuscripts should be sent to the Editor, June K. Robinson, MD, Loyola University Chicago, Division of Dermatology, 2160 S First Ave, Bldg 112, Room 341, Maywood, IL 60153 USA; telephone: (708) 216-8602; fax: (708) 216-8182; e-mail: archdermatol@jama-archives.org.

Manuscripts are considered with the understanding that they have not been published previously in print or electronic format and are not under consideration by another publication or electronic medium. A complete report following presentation or publication of preliminary findings elsewhere (eg, in an abstract) can be considered. Include copies of possibly duplicative material that has been previously published or is currently being considered elsewhere.¹ Authors submitting manuscripts or letters to the editor regarding adverse drug or medical device reactions, reportable diseases, and the like should also report such to the relevant government agency.

Electronic Submission.—We encourage authors to submit manuscripts via e-mail to archdermatol@jama-archives.org. Manuscripts submitted by e-mail should not be submitted by mail or fax. Please note that the required author responsibility form must still be submitted by mail or fax. To ensure that the

electronic submission is usable, please adhere to the following guidelines when submitting your manuscript electronically.

- In the subject line of the e-mail, type “Electronic submission.” In the e-mail message include your full name, e-mail address, mailing address, and telephone and fax numbers, and the title of the manuscript as it appears on the cover page of the attached file.
- Text and tables should be in the same file, if possible.
- **Text:** Save the text in Microsoft Word.
- **Tables:** Save any tables in the same file. Make certain that each item in the table sits in its own table cell. Do not use paragraph returns (to start new rows) or tabs (to start new columns) to format the table.
- **Figures:** Images should be saved as separate files in either JPG or TIFF format, indicating the author name and submission date in the file name. Please note that some e-mail systems will not process large attachments, so these files may need to be e-mailed separately. Please refer to “Digital Art Submissions” elsewhere in these Instructions for proper formatting and resolution requirements. Digitally enhanced images must be identified in the figure legends as electronically enhanced or manipulated. Please include and clearly label the enhanced images and the original images for review by our reviewers. Enhanced images are also to be submitted by mail as 3 hard copies of the enhanced images and 3 hard copies of the original images for review by our reviewers.
- **Copyright Form and Patient Consent:** Upon submission, the corresponding author should fax the completed author responsibility forms for all authors to the editorial office: (708) 216-8182. On the fax cover page, please indicate that these forms are for a manuscript submitted electronically and include the date of submission. At the same time, please send a signed statement of informed consent to publish (in print and online) patient photographs and pedigrees from all persons who can be identified in such photographs and pedigrees.
- Manuscripts submitted by e-mail should not also be submitted by regular mail or fax; however, if the manuscript is accepted for publication, we will need 3 hard copies of the manuscript and glossies of the figures, as well as 2 sets of slides for each color illustration. We will also need the text, tables, and figures on a diskette or CD at this stage.

Embargo Policy.—Information regarding the content and publication date of accepted manuscripts is confidential. Information contained in or about accepted articles cannot appear in print, radio, television, or in electronic form or be released to the media until 3 PM CST on the third Monday of the month.

Categories of Articles

The *Archives of Dermatology* publishes original contributions (Studies), case reports and series (Observations), review articles, brief reports, special communications, commentaries, letters to the editor, and many other categories of articles. Topics of interest include all subjects that are related to the practice of dermatology and the betterment of public health worldwide. The most frequent categories of articles are described below.

Studies.—Randomized controlled trials (see “Instructions for Preparing Reports of Randomized Controlled Trials”), intervention studies, studies of screening and diagnostic tests, out-

About the ARCHIVES

- The ARCHIVES desires to publish clinical and laboratory studies that enhance the understanding of skin and its diseases. In addition to these STUDIES, case reports that substantially add to our knowledge in a meaningful fashion will be published as OBSERVATIONS.
- The CIRCULATION of the ARCHIVES is among the highest of any dermatologic publication in the world—currently over 14 000. The journal is received by virtually all requesting US physicians—including first-, second-, and third-year residents—who practice dermatology as their primary specialty as self-designated in the AMA Physician Masterfile. Inquiries should be directed to the American Medical Association, Subscription Services Center, 515 N State St, Chicago, IL 60610; (312) 670-7827.
- EXPEDITED REVIEW AND PUBLICATION is possible on request from the authors in the transmittal letter.
- FREE COLOR PUBLICATION is available if printing illustrations in color adds greatly to the didactic value of the article. See “Illustrations” section below for detailed instruction.
- RAPID REVIEW AND PUBLICATION is the policy of the ARCHIVES. Our acceptance rate for all manuscripts for the year 2002 was 46%.

come studies, cost-effectiveness analyses, case-control series, and surveys with high response rates. Each manuscript should clearly state an objective or hypothesis; the design and methodology (including the study's setting and time period, patients or participants with inclusion and exclusion criteria, or data sources and how these were selected for the study); the essential features of any interventions; the main outcome measures; the main results of the study; a discussion placing the results in the context of published literature; and the conclusions. For more information, see "Instructions for Preparing Structured Abstracts." Typical length: 8 to 20 double-spaced manuscript pages (not including tables, figures, and references).

Observations.—Short reports of original studies or evaluations. Clinical cases (individual or a series) that are unique and of high didactic value. Typical length: 3 to 9 double-spaced manuscript pages (not including tables, figures, and references).

Reviews.—Systematic critical assessments of literature and data sources pertaining to clinical topics, emphasizing factors such as cause, diagnosis, prognosis, therapy, or prevention. All articles and data sources reviewed should include information about the specific type of study or analysis, population, intervention, exposure, and tests or outcomes. All articles or data sources should be selected systematically for inclusion in the review and critically evaluated, and the selection process should be described in the paper. Meta-analyses also will be considered as reviews. For more information, see "Instructions for Preparing Structured Abstracts." Typical length: 15 to 20 double-spaced manuscript pages (not including tables, figures, and references).

Cutting Edge.—Clinicians, local and regional societies, residents, and fellows are invited to submit cases of challenges in management and therapeutics to this section. Cases should follow the established pattern. If submitting by mail, submit 4 double-spaced copies of the manuscript with right margins nonjustified and 4 sets of the illustrations. Photomicrographs and illustrations must be clear and submitted as positive color transparencies (35-mm slides) or black-and-white prints. Do not submit color prints unless accompanied by original transparencies. Material should be accompanied by the required copyright transfer statement. Material for this section should be submitted to George J. Hruza, MD, Laser and Dermatological Surgery Center Inc, 14377 Woodlake Dr, Suite 111, St Louis, MO 63017 (e-mail: ghruza@aol.com). If submitting electronically, please see guidelines under "Electronic Submission" elsewhere in these Instructions.

Critical Situations.—Readers are invited to submit examples of acute or potentially life-threatening disorders that highlight important, new, or difficult diagnostic or therapeutic challenges. Case reports should be submitted using the established "Critical Situations" format, with "Report of a Case," "Challenge," and "Comment" sections. Material should be submitted to Anita G. Licata, MD, University of Vermont, Division of Dermatology, Fletcher Allen Health Care/University Health Center, 1 S Prospect St, Burlington, VT 05401-3444 (e-mail: Anita.Licata@vtmednet.org). Manuscripts may be submitted electronically via e-mail (see "Electronic Submission"). If submitting by mail, submit 4 double-spaced copies of the manuscript with right margins nonjustified, 4 sets of the illustrations, and a diskette.

Off-Center Fold.—Clinicians, local and regional societies, and residents and fellows in dermatology are invited to submit quiz cases to this section. Cases should follow the established pattern and be submitted double-spaced. Photomicrographs and illustrations must be clear and submitted as 3 positive color transparencies and as 3 color prints. Material should be accompanied by the required copyright transfer statement. Material for this section should be submitted to Michael E. Ming,

Manuscript Checklist

- 1. Include original manuscript, 3 photocopies, and diskette, if submitting by mail.
- 2. If submitting by e-mail, include text, tables, and figures in a single file (if possible), as well as mailing address, telephone and fax numbers, and e-mail address.
- 3. Include statements—signed by each author—on (a) authorship criteria and responsibility, (b) financial disclosure, (c) copyright transfer or federal employment, and (d) acknowledgment statement.
- 4. Indicate general and specific contributions from each author (see authorship checklist).
- 5. Include statement signed by corresponding author that written permission has been obtained from all persons named in the acknowledgment.
- 6. Include research or project support/funding in an acknowledgment.
- 7. Double-space manuscript (text and references) and leave right margins unjustified (ragged).
- 8. Check all references for accuracy and completeness. Put references in proper format in numerical order, making sure each is cited in the text.
- 9. If submitting by mail, send 4 sets of all illustrations. If submitting electronically, send JPG or TIFF files. NOTE: The file cannot be larger than 2 MB. If larger, then please send as separate e-mail attachments.
- 10. Provide and label an abstract.
- 11. Include written permission from each individual identified as a source for personal communication.
- 12. Include informed consent forms for identifiable patient descriptions, photographs, and pedigrees.
- 13. Include written permission from publishers or other copyright holders to reproduce or adapt previously published illustrations and tables in print and online editions of *Archives of Dermatology* and its licensed versions.
- 14. On the title page, designate a corresponding author and provide a complete address, telephone and fax numbers, e-mail address, and word count.

MD, Department of Dermatology, University of Pennsylvania Health System, 2 Maloney Bldg, 3600 Spruce St, Philadelphia, PA 19104-4283.

skINsight.—Readers are invited to submit visually compelling images with striking patterns whose recognition enhances our diagnostic and therapeutic abilities. The submission may include up to 3 figures and the text must be no more than 200 words. You may submit your manuscript by mail or e-mail to James M. Grichnik, MD, PhD, Duke University Medical Center, Department of Medicine, PO Box 3135, Durham, NC 27710-3135 (e-mail: grich001@mc.duke.edu). If submitting by mail, submit 4 double-spaced copies of the manuscript with right margins nonjustified, 4 sets of the illustrations, and a diskette.

Correspondence.—The Correspondence section of the ARCHIVES is meant to provide a forum for exchange of ideas about cutaneous medicine and surgery and is divided into 2 sections. The Comments and Opinions section is intended for responses to articles previously published in the journal or for comments on philosophic and practical issues pertaining to dermatology. If an ARCHIVES article is discussed, the letter should contain this reference and be received within 4 months of the article's publication. The Vignettes section contains short studies, very short case reports, rapid publications, and preliminary observations that lack the data to qualify as full journal articles. Acceptance is contingent on

editorial review and space available. Correspondence should be typewritten, double-spaced, submitted in triplicate, and clearly marked "for publication." Correspondence should not exceed 500 words, should not contain more than 5 references and 2 figures, and must include a copyright transfer statement when submitted.

Criteria for Manuscript Acceptance

Manuscripts submitted to the *Archives of Dermatology* should meet the following criteria: the material is original; the writing is clear; the study methods are appropriate; the data are valid; the conclusions are reasonable and supported by the data; the information is important; and the topic has general medical interest. From these basic criteria, we assess a paper's eligibility for publication. We receive approximately 800 papers each year, but publish only about 40% of unsolicited manuscripts. Because of this competition for space in the *Archives of Dermatology*, we advise authors to follow these instructions and to keep papers as brief as possible while still meeting the quality criteria described above.

Authorship Information

Designate 1 author as corresponding author and provide a complete address, telephone and fax numbers, and e-mail address. Manuscripts with 6 or more authors should include a justification or explanation of each author's contribution. Authors may add a publishable footnote explaining order of authorship and specific contributions.^{2,3}

Data Access and Responsibility. For reports containing original data, at least 1 author (eg, the principal investigator) should indicate that he or she "had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis."⁴

Group Authorship. If authorship is attributed to a group (either solely or in addition to 1 or more individual authors), all members of the group must meet the full criteria and requirements for authorship described in the following paragraphs. A group must designate at least 1 or more individuals as authors or members of a writing group who meet full authorship criteria and requirements and who will take responsibility for the group, in which case the other group members are not authors, but may be listed in an acknowledgment.⁵

Authorship Requirements. With the cover letter include (1) the statement on authorship criteria and responsibility and (2) the statement on financial disclosure and (3) either the statement on copyright or the statement on federal employment. Each of these 3 statements must be read and signed by *all* authors.⁶ (4) The corresponding author must sign the acknowledgment statement. (See the form at the end of these Instructions.)

1. Authorship Responsibility, Criteria, and Contributions Checklist. Each author should meet all criteria below and should indicate general and specific contributions by reading criteria A, B, C, and D and checking the appropriate boxes.

A. I certify that

- the manuscript represents valid work and that neither this manuscript nor one with substantially similar content under my authorship has been published or is being considered for publication elsewhere, except as described in an attachment; and
- if requested by the editors, I will provide the data or will cooperate fully in obtaining and providing the data on which

the manuscript is based for examination by the editors or their assignees; and

- for papers with more than 1 author, I agree to allow the corresponding author to serve as the primary correspondent with the editorial office, to review the edited typescript and proof, and to make decisions regarding release of information in the manuscript to the media, federal agencies, or both; or, if I am the only author, I will be the corresponding author and agree to serve in the roles described above.

B. I have given final approval of the submitted manuscript.

C. I have participated sufficiently in the work to take public responsibility for (check 1 of 2 below)

- part of the content.
- the whole content.

D. To qualify for authorship, you must check at least 1 box for each of the 3 categories of contributions listed below.

I have made substantial contributions to the intellectual content of the paper as described below.

1. (check at least 1 of the 3 below)

- conception and design
- acquisition of data
- analysis and interpretation of data

2. (check at least 1 of 2 below)

- drafting of the manuscript
- critical revision of the manuscript for important intellectual content

3. (check at least 1 below)

- statistical expertise
- obtaining funding
- administrative, technical, or material support
- supervision
- no additional contributions
- other (specify) _____

2. Financial Disclosure.

• I certify that all financial and material support for this research and work are clearly identified in the manuscript.

• I certify that all my affiliations with or financial involvement (eg, employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, royalties) with any organization or entity with a financial interest in or in financial conflict with the subject matter or materials discussed in the manuscript are completely disclosed here or in an attachment.

I have no relevant financial interests in this manuscript.

3. Copyright Transfer.—"In consideration of the action of the American Medical Association (AMA) in reviewing and editing this submission, the author(s) undersigned hereby transfer(s), assign(s), or otherwise convey(s) all copyright ownership to the AMA in the event that such work is published by the AMA."

Federal Employment.—"I was an employee of the US federal government when this work was investigated and prepared for publication; therefore, it is not protected by the Copyright Act and there is no copyright of which the ownership can be transferred."

4. Acknowledgment Statement.—The corresponding author must include the following statement in the cover letter: "All persons who have made substantial contributions to the work reported in the manuscript (including writing and editing assistance), but who are not authors, are named in the acknowledgment and have given me their written permission to be

named. If I do not include an acknowledgment, that means I have not received substantial contributions from nonauthors." (See the form at the end of these Instructions.) Authors should obtain written permission from all individuals named in an acknowledgment, since readers may infer their endorsement of data and conclusions.³

Editorial Review and Processing

Peer Review.—All submitted manuscripts are reviewed initially by an ARCHIVES editor. Those manuscripts with insufficient priority for publication are rejected promptly. Other manuscripts are sent to expert consultants for peer review. Peer reviewer identities are kept confidential. Author identities are not kept confidential.

The existence of a manuscript under review is not revealed to anyone other than peer reviewers and editorial staff. Information from submitted manuscripts may be systematically collected and analyzed as part of research to improve the quality of the editorial or peer review process. Identifying information remains confidential.

Rejected Manuscripts.—Rejected manuscripts will not be returned to authors unless specifically requested in the cover letter. Original illustrations, photographs, and slides for rejected manuscripts only will be returned.³

Editing.—Accepted manuscripts are copyedited according to AMA style⁷ and returned to the author for approval. Authors are responsible for all statements made in their work, including changes made by the copy editor and authorized by the corresponding author.

Reprints.—Reprint order forms are included with the edited typescript sent for approval to the corresponding author. Reprints are shipped 3 weeks after publication.

All published manuscripts become the permanent property of the AMA and may not be published elsewhere without written permission from the AMA.

Manuscript Preparation

- Manuscripts should be prepared in accordance with the *American Medical Association Manual of Style*⁷ and/or the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals."⁸

- Submit the original manuscript and 3 photocopies; use 1 side of standard-sized white bond paper and 1-inch margins. Please include a diskette containing the text of your manuscript and any tables, figures, and line art. Specify the following on the diskette: first author, computer operating system, and word-processing software used. For digital images, submit as CDs (see guidelines under "Digital Art Submissions").

- Double-space throughout, including title page, abstract, text, acknowledgments, references, legends for illustrations, and tables. Start each of these sections on a new page, numbered consecutively, beginning with the title page. Use only standard 10- or 12-point font size. Do not use proportional spacing; use unjustified (ragged) right margins and letter-quality printing.

- On the title page, include a word count for text only, exclusive of title, abstract, references, tables, and figure legends.

- On the title page include the full names, highest academic degrees, and affiliations of all authors. If an author's affiliation has changed since the work was done, list the new affiliation as well.

- Conventional units of measure are preferred, with Sys-

tème International (SI) units given in parentheses. Exceptions to this rule include calories, hematocrit, blood cell counts, and ejection fraction, for which conventional units alone are sufficient. In tables and figures, use conventional units and give the conversion factor for SI units in a footnote or legend. The metric system is preferred for the expression of length, area, mass, and volume.

- Use generic names of drugs, unless the specific trade name of a drug used is directly relevant to the discussion.
- Do not use abbreviations in the title or abstract and limit their use in the text.

Abstract.—Include a *structured abstract* of no more than 250 words for reports of studies, reviews (including meta-analyses), and consensus statements and no longer than 200 words for observations. (See "Instructions for Preparing Structured Abstracts.") For other major manuscripts, include a conventional, unstructured abstract of no more than 150 words. Abstracts are not required for Editorials, Commentaries, and special features of the *Archives of Dermatology*.

Informed Consent.—For experimental investigations of human or animal subjects, state in the "Methods" section of the manuscript that an appropriate institutional review board approved the project. For those investigators who do not have formal ethics review committees (institutional or regional), the principles outlined in the Declaration of Helsinki should be followed.⁹ For investigations of human subjects, state in the "Methods" section the manner in which informed consent was obtained from the subjects.

Patient Descriptions, Photographs, and Pedigrees.—Include a signed statement of informed consent to publish (in print and online) patient descriptions, photographs, and pedigrees from all persons (parents or legal guardians for minors) who can be identified in such written descriptions, photographs, or pedigrees. Such persons should be offered the opportunity to see the manuscript before submission. (See patient consent form online at <http://archderm.ama-assn.org/cgi/content/full/140/1/!!!SWK-a!!!!/DC1>.)

Personal Communications.—Include a signed statement of permission from each individual identified as a source of information in a personal communication, either written or oral communication.

References.—Number references in the order they are mentioned in the text; do not alphabetize. In text, tables, and legends, identify references with superscript arabic numerals. When listing references, follow AMA style,⁶ abbreviating names of journals according to *Index Medicus*. Note: List all authors and/or editors up to 6; if more than 6, list the first 3 and "et al."

Web References. Please keep a print copy of any reference to Web-only information. If the URL changes or disappears, interested readers may contact the corresponding author for a copy of the information.

Examples of Reference Style:

REFERENCES

1. Chung JH, Yano K, Lee MK, et al. Differential effects of photoaging vs intrinsic aging on the vascularization of human skin. *Arch Dermatol*. 2002;138:1437-1442.
2. Arndt KA, Dover JS, eds. *Controversies & Conversations in Cutaneous Laser Surgery*. Chicago, Ill: AMA Press; 2002.
3. Kinsella K, Velkoff VA. *An Aging World: 2001*. Available at: <http://www.census.gov/prod/2001pubs/p95-01-1.pdf>. Accessed November 8, 2002.

Authors are responsible for the accuracy and completeness of their references and for correct text citation.

Tables.—Title all tables and number them in order of their citation in the text. Double-space each table on separate sheets of standard-sized white bond paper. If a table must be continued, repeat the title on a second sheet, followed by “(cont).”

Illustrations.—Submit 4 sets of all illustrations: (1) 5×7-inch matte-finish (or glossy) photographs for all graphs and black-and-white photographs (computer-generated graphs produced by high-quality laser printers also are acceptable); (2) high-contrast prints for x-ray films; (3) color slides (and corresponding color prints) for color illustrations. Number illustrations according to their order in the text. Affix a label with figure number, name of first author, short form of the manuscript title, and an arrow indicating “top” to the back of the print. Never mark on the print or the transparency itself. Original illustrations, photographs, and slides from rejected manuscripts will be returned to authors. For accepted manuscripts, these will be returned on request only.

Digital Art Submissions.—RGB color submissions are preferred. Calibrated color proofs should be submitted with color digital files, if possible. The canvas size of continuous-tone images should be at least 5 inches wide (depth not important) with an image resolution of at least 350 ppi. Line art images should have a minimum resolution of 1270 ppi. Formats accepted are EPS, TIFF, and JPG. Digital art may be transferred by CDs or e-mail if it is not larger than 2 MB. Compress the files using software, such as WinZip or StuffIt.

Legends.—Double-space legends (maximum length, 40 words) on separate pages. Indicate magnification and stain used for photomicrographs. Digitally enhanced images must be clearly identified in the figure legends as enhanced or manipulated, eg, computed tomographic scans, magnetic resonance images, photographs, photomicrographs, x-ray films.

Adapting or Reproducing Tables and Illustrations.—Acknowledge all illustrations and tables adapted or reproduced from other publications and submit written permission to reproduce (in print and online) from the original publishers. (See permission form online at <http://archderm.ama-assn.org/cgi/content/full/140/1/!!!SWK-a!!!/DC2>.)

REFERENCES

1. Lundberg GD. Statement by the International Committee of Medical Journal Editors on duplicate or redundant publication. *JAMA*. 1993;270:2495.
2. International Committee of Medical Journal Editors. Statements from the International Committee of Medical Journal Editors. *JAMA*. 1991;265:2697-2698.
3. Glass RM. New information for authors and readers: group authorship, acknowledgments, and rejected manuscripts [published correction appears in *JAMA*. 1993; 269:48]. *JAMA*. 1992;268-99.
4. DeAngelis CD, Fontanarosa PB, Flanagin A. Reporting financial conflicts of interest and relationships between investigators and research sponsors. *JAMA*. 2001;286:89-91.
5. Flanagin A, Fontanarosa PB, DeAngelis CD. Authorship for research groups. *JAMA*. 2002;288:3166-3168.
6. Lundberg GD, Flanagin A. New requirements for authors: signed statements of authorship responsibility and financial disclosure. *JAMA*. 1989;262:2003-2004.
7. Iverson CL, Flanagin A, Fontanarosa P, et al. *American Medical Association Manual of Style*. 9th ed. Baltimore, Md: Williams & Wilkins; 1998.
8. International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Available at: <http://www.icmje.org>.
9. 41st World Medical Assembly. Declaration of Helsinki: recommendations guiding physicians in biomedical research involving human subjects. *JAMA*. 1997; 277:925-926.

INSTRUCTIONS FOR PREPARING REPORTS OF RANDOMIZED CONTROLLED TRIALS

The checklist (**Table**) should be completed and submitted with the manuscript. In addition, include a flow diagram illustrating the progress of patients throughout the trial (**Figure**).

The checklist and flow diagram will be reviewed along with the manuscript. If the manuscript is accepted, the flow diagram will be published.

INSTRUCTIONS FOR PREPARING STRUCTURED ABSTRACTS

All reports of original data, reviews, including meta-analyses, and consensus statements should be submitted with structured abstracts as described below. The following is adapted from Haynes RB, Mulrow CD, Huth EJ, Altman DG, Gardner MJ. More informative abstracts revisited. *Ann Intern Med*. 1990; 113:69-76.

Reports of Original Data

Authors submitting manuscripts reporting original data should prepare an abstract of no more than 250 words under the following headings: Objective, Design, Setting, Patients (or Other Participants), Interventions (if any), Main Outcome Measure(s), Results, and Conclusions. The content following each heading should be as follows:

1. **Objective.**—The abstract should begin with a clear statement of the precise objective or question addressed in the report. If more than 1 objective is addressed, the main objective should be indicated and only key secondary objectives stated. If an a priori hypothesis was tested, it should be stated.

2. **Design.**—The basic design of the study should be described. The duration of follow-up, if any, should be stated. As many of the following terms as apply should be used.

A. Intervention studies: randomized control trial; nonrandomized control trial; double-blind; placebo control; crossover trial; before-after trial.

B. For studies of screening and diagnostic tests: “gold standard” (ie, a widely accepted standard with which a new or alternative test is being compared); blinded or masked comparison.

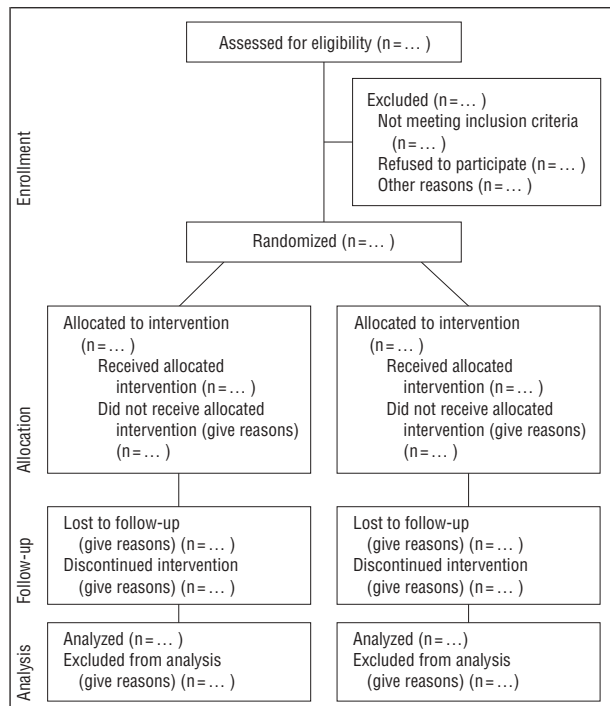
C. For studies of prognosis: inception cohort (subjects assembled at a similar and early time in the course of the disorder and followed thereafter); cohort (subjects followed forward in time, but not necessarily from a common starting point); validation cohort or validation sample if the study involves the modeling of clinical predictions.

D. For studies of causation: randomized control trial; cohort; case-control; survey (preferred to “cross-sectional study”).

Checklist of Items to Include When Submitting Reports of Randomized Controlled Trials to the *Archives of Dermatology**

Section and Topic	Item	Descriptor	Was It Reported? Yes or No?	If Yes, What Page No.?
Title and abstract	1	How participants were allocated to interventions (eg, "random allocation," "randomized," or "randomly assigned").	___	___
Introduction				
Background	2	Scientific background and explanation of rationale.	___	___
Methods				
Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	___	___
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	___	___
Objectives	5	Specific objectives and hypotheses.	___	___
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors).	___	___
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	___	___
Randomization				
Sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (eg, blocking, stratification).	___	___
Allocation concealment	9	Method used to implement the random allocation sequence (eg, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	___	___
Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	___	___
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.	___	___
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses.	___	___
Results				
Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	___	___
Recruitment	14	Dates defining the periods of recruitment and follow-up.	___	___
Baseline data	15	Baseline demographic and clinical characteristics of each group.	___	___
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat." State the results in absolute numbers when feasible (eg, 10/20, not 50%).	___	___
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (eg, 95% confidence interval).	___	___
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory.	___	___
Adverse events	19	All important adverse events or side effects in each intervention group.	___	___
Comment				
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes.	___	___
Generalizability	21	Generalizability (external validity) of the trial findings.	___	___
Overall evidence	22	General interpretation of the results in the context of current evidence.	___	___

*This checklist of 22 items is intended to assist authors, editors, and reviewers by ensuring that information pertinent to the trial is included in the study report. Adapted from Moher D, Schulz KF, Altman D, for the CONSORT Group. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *JAMA*. 2001;285:1987-1991.



Flow diagram of subject progress through the phases of a randomized trial. Adapted from Moher D, Schulz KF, Altman D, for the CONSORT Group. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *JAMA*. 2001;285:1987-1991.

E. For descriptions of the clinical features of medical disorders: survey; case series.

F. For studies that include a formal economic evaluation: cost-effectiveness analysis; cost-utility analysis; cost-benefit analysis.

For new analyses of existing data sets, the data set should be named and the basic study design disclosed.

3. Setting.—To assist readers to determine the applicability of the report to their own clinical circumstances, the study setting(s) should be described. Of particular importance is whether the setting is the general community, a primary care or referral center, private or institutional practice, ambulatory or hospitalized care.

4. Patients or Other Participants.—The clinical disorders, important eligibility criteria, and key sociodemographic features of patients should be stated. The numbers of participants and how they were selected should be provided (see below), including the number of otherwise eligible subjects who were approached but refused. If matching is used for comparison groups, characteristics that are matched should be specified. In follow-up studies, the proportion of participants who completed the study must be indicated. In intervention studies, the number of patients withdrawn for adverse effects should be given.

For selection procedures, these terms should be used, if appropriate: random sample (where “random” refers to a formal, randomized selection in which all eligible subjects have a fixed and usually equal chance of selection); population-based sample; referred sample; consecutive sample; volunteer sample; convenience sample. These terms assist the reader to determine an important element of the generalizability of the

study. They also supplement (rather than duplicate) the terms used by professional indexers when articles are entered into computerized databases.

5. Intervention(s).—The essential features of any interventions should be described, including their method and duration of administration. The intervention should be named by its most common clinical name (for example, the generic term *chlorthalidone*). Common synonyms should be given as well to facilitate electronic textword searching. This would include the brand name of a drug if a specific product was studied.

6. Main Outcome Measure(s).—The primary study outcome measurement(s) should be indicated as planned before data collection began. If the paper does not emphasize the main planned outcomes of a study, this fact should be stated and the reason indicated. If the hypothesis being reported was formulated during or after data collection, this information should be clearly stated.

7. Results.—The main results of the study should be given. Measurements that require explanation for the expected audience of the manuscript should be defined. Important measurements not included in the presentation of results should be declared. As relevant, it should be indicated whether observers were blinded to patient groupings, particularly for subjective measurements. Due to the current limitations of retrieval from electronic databases, results must be given in narrative or point form rather than tabular form if the abstract is to appear in computerized literature services such as MEDLINE. The results should be accompanied by confidence intervals (for example, 95%) and the exact level of statistical significance. For comparative studies, confidence intervals should relate to the differences between groups. For nonsignificant differences for the major study outcome measure(s), the clinically important difference sought should be stated and the confidence interval for the difference between the groups should be given. When risk changes or effect sizes are given, absolute values should be indicated so that the reader can determine the absolute as well as relative impact of the finding. Approaches such as “number needed to treat” to achieve a unit of benefit are encouraged when appropriate; reporting of relative differences alone is usually inappropriate. If appropriate, studies of screening and diagnostic tests should use the terms *sensitivity*, *specificity*, and *likelihood ratio*. If predictive values or accuracy is given, prevalence or pretest likelihood should be given as well. No data should be reported in the abstract that do not appear in the rest of the manuscript.

8. Conclusions.—Only those conclusions of the study that are directly supported by the evidence reported should be given, along with their clinical application (avoiding speculation and overgeneralization), and indicating whether additional study is required before the information should be used in usual clinical settings. Equal emphasis must be given to positive and negative findings of equal scientific merit.

To permit quick and selective scanning, the headings outlined above should be included in the abstract. For brevity, parts of the abstract can be written in phrases rather than complete sentences. (For example: “2. Design. Double-blind randomized trial,” rather than “2. Design. The study was conducted as a double-blind, randomized trial.”) This technique may make reading less smooth but facilitates selection scanning and allows more information to be conveyed per unit of space.

Observation Manuscripts

Abstracts that accompany publication of Observations should be no longer than 200 words and described under 3 headings.

1. **Background.** Give an overview of the topic and discuss the main objective or reason for this report. Why was this manuscript submitted for publication and how is the information included unique?
2. **Observations.** State the principal observations, findings, or results. Numerical results should include confidence intervals and levels of statistical significance if applicable.
3. **Conclusions.** Give the conclusions of the report that are supported by the information, along with clinical applications, avoiding overgeneralization. The need for further studies or additional research may be suggested.

Review Manuscripts (Including Meta-analyses)

Authors submitting review manuscripts and reports of the results of meta-analyses should prepare an abstract of no more than 250 words under the following headings: Objective, Data Sources, Study Selection, Data Extraction, Data Synthesis, and Conclusions. The manuscript should also include a section addressing the methods used for data sources, study selection, data extraction, and data synthesis. Each heading should be followed by a brief description:

1. **Objective.**—The abstract should begin with a precise statement of the primary objective of the review. The focus of this statement should be guided by whether the review emphasizes factors such as cause, diagnosis, prognosis, therapy, or prevention. It should include information about the specific population, intervention, exposure, and test or outcome that is being reviewed.
2. **Data Sources.**—A succinct summary of data sources should be given, including any time restrictions. Potential sources include experts or research institutions active in the field, computerized databases and published indexes, registries, abstract booklets, conference proceedings, references identified from bibliographies of pertinent articles and books, and companies or manufacturers of tests or agents being reviewed. If a bibliographic database is used, the exact indexing terms used for article retrieval should be stated, including any constraints (for example, English language or human subjects).
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6. **Conclusions.**—The conclusions and their applications should be clearly stated, limiting generalization to the domain of the review. The need for new studies may be suggested.

Consensus Statements

Authors submitting manuscripts reporting consensus statements should prepare an abstract of no more than 250 words under the following headings: Objective, Participants, Evidence, Consensus Process, and Conclusions. This format should also be used to report clinical practice guidelines that were developed by consensus. While the descriptions are summarized in the abstract, they should be expanded in the text. References supporting the text should be provided. The content under each heading is as follows:

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