CRIC Study Publications Policy

I. Overview

A. The success of the CRIC Study will depend largely on the number and quality of its scientific publications and presentations. The purpose of the policy established herein is to encourage and facilitate the presentation of CRIC Study analyses while providing guidelines that ensure appropriate use of the CRIC data, timely completion of manuscripts and presentations, equitable access to authorship, and adherence to established principles of authorship.

B. For the purposes of this policy, *CRIC Investigators* are all individuals affiliated with the CRIC Study to whom this policy will apply. The *CRIC Investigators* are categorized into four groups:

i) CRIC PIs
- (1) CRIC Principal Investigators
- (2) NIDDK Project Scientist

ii) CRIC Core Investigators
- (1) Typically, but not necessarily limited to investigators who are Key Personnel at the Clinical Centers and the Scientific and Data Coordinating Center (SDCC) other than *CRIC PIs, including* PIs of Central Reading Centers and Laboratories.
- (2) *CRIC PIs* will be responsible for identifying the *CRIC Core Investigators* at their sites annually or as often as changes in this group occur.

iii) CRIC Team Members
- (1) Investigators with a more limited role (e.g., investigators participating in recruitment or in some other focused aspect of the study, investigators invited to participate by the Steering Committee in specific analyses based on expertise, previous CRIC investigators who left the study, consultants).
- *(2)* Research staff
- (3) Trainees
  - (a) Trainees funded to maintain an active role on the CRIC Study.
  - (b) Students or fellows with an active but temporary role.
  - (c) *CRIC PIs* will be responsible for identifying *Trainees* at their sites annually or more often if changes in this group occur.

iv) *Ancillary Investigators*
- (1) Individuals who propose, receive approval, and obtain funding for a research project, but have no other roles in either local implementation or on study-wide committees.

C. CRIC investigators may submit requests to lead a manuscript to the Pub Exec committee utilizing CRIC data, pursuing research questions not otherwise approved as the focus of prior manuscript proposals or as specific aims of approved ancillary studies.

II. Publication Policy Principles

A. Publication of scientific research papers is a central and critical aspect of the CRIC Study because:

i) Scientific publications will be the principal mechanism by which the CRIC Study will communicate its scientific findings.
ii) Scientific publications represent one of the most important mechanisms for CRIC Investigators to achieve scientific and academic recognition for their participation in CRIC.

B. Research questions and hypotheses to be addressed using CRIC Study data should be formulated *a priori* and clearly stated in a manuscript proposal to reduce the likelihood that study results are attributable to type I error.
   i) When an approved manuscript activity diverges from the established analytical plan, the authors of any resulting manuscript are urged to be transparent in their discussion of the possible implications for the level of type 1 error and assessments of statistical significance.
   ii) In the event that a new research question and hypothesis is generated during analyses, the authors are similarly urged to be transparent in their discussion of the possible implications for the level of type 1 error and assessments of statistical significance.
C. Publication policies should promote scientific inquiry within and productivity from the CRIC Study.
D. Publication of scientific findings from the CRIC Study should proceed in a timely fashion once relevant analyses are complete.
E. Abstracts, presentations, and publications based on CRIC material must be accurate and objective and must not compromise the scientific integrity of the CRIC study.
F. The publications arising from the CRIC Study should avoid overlap and conflicting representation of CRIC Study findings.
G. Recognition through authorship will be distributed among the *CRIC Investigators* so that:
   i) All *CRIC PIs* have equitable opportunity to lead and co-author CRIC publications
   ii) All *CRIC Core Investigators* have the opportunity to lead and co-author CRIC publications.
   iii) All *CRIC Team Members* have opportunity to participate in publications reporting scientific findings to which they have contributed.
   iv) All *CRIC Team Members* have opportunity to lead and be co-authors on publications resulting from analyses made possible through their collaboration.
   v) All *Ancillary Investigators* have the opportunity to lead and be co-authors on publications resulting from analyses made possible through their collaboration.
H. The CRIC Study promotes the career development of trainees and junior faculty by providing them opportunity to lead and to be recognized as co-authors of CRIC publications.
   i) This policy provides a framework for balancing career development considerations against the legitimate interests of *CRIC PIs* and *CRIC Core Investigators* to lead CRIC publications.
I. Authorship on CRIC publications will adhere to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals of the International Committee of Medical Journal Editors. (See attached.)

III. Structure of the Publications Executive committee

A. Implementation of this Publications Policy and management of day-to-day activities will be the responsibility of the CRIC Publications Executive committee, (abbreviated as the

Pub Exec committee for the remainder of this document). The Pub Exec committee will consist of The PI and Co-PI of the SDCC, a representative from the NIDDK, and two Clinical Center PIs or designated Core Investigators. Nominations for Chair and co-Chair of the Pub Exec committee are assembled by the SDCC from all voting members of the CRIC Steering Committee. If more than 2 nominees are identified, a vote will be taken to identify 2 individuals to serve in this role. The term of these appointments will be for 2 years, renewable by an affirmative vote of 7 or more members of the Steering Committee.

B. The SDCC will provide staffing for the Pub Exec committee. One member of the project management staff will have primary responsibility to serve as a liaison to this committee and should receive copies of all relevant correspondence. This individual will be identified on the CRIC Study web site. Send all communications to the CRIC Pub Exec committee in care of this SDCC staff member. Current addresses are listed on the CRIC web site (www.cristudy.org).

IV. Procedures

A. Submission of Proposals for Scientific Papers

i) Proposals for manuscripts likely will arise from a number of sources including, but not limited to, the CRIC Investigators and CRIC ancillary study investigators. A proposal from a CRIC Clinical Center requires approval by that Center's Principal Investigator before submission to the Pub Exec committee. Those who propose scientific papers must present these formally to the Pub Exec committee. The proposal must include "Summary Information" and a brief description of "Proposal Details."

(1) Summary Information

(a) Date
(b) Full Proposal Title
(c) Abbreviated Title (Up to 50 letters and spaces)
(d) Proposed Writing Committee (Including sponsor if first author is not a *CRIC Investigator*)
(e) Proposed Writing Committee members
(i) **The number of nominated authors/co-authors listed on submitted manuscript proposals should be limited to five. By limiting the number of nominated authors/co-authors to 5, we will increase the number of potential co-authors drawn from the broader CRIC community and ensure the author list stays under a target maximum of 15. With 5 nominated authors/co-authors on the initial submission, the proposing team will be able to include initiating investigators and core members of the analytical team.**
(ii)
(f) Abstract/Brief Description (Events, Longitudinal, Cross-sectional, Methods)
(g) Type of Manuscript (Main, Ancillary Study, Title & PI for Ancillary)
(h) Data Analysis locations (SDCC or Local) and timing (interim data needed?)
(i) Keywords and Domain (if applicable)
(j) Additional Comments

(2) Proposal Details

(a) Introduction (Brief rationale and background)
(b) Research Hypothesis (Clear statement of scientific questions to be addressed)
(a) Introduction
(b) Research Hypothesis
(c) Data (List of variables to be used, biological samples including volume of samples if relevant)
(d) Analysis plan and methods in consultation with the SDCC (Detailed description of proposed statistical analyses)
(e) Relationship of the proposed manuscript to other CRIC abstracts, manuscripts, approved/pending manuscript proposals, and specific aims of approved ancillary studies.
(f) Proposed mock-up tables and figures
(g) Proposed journal(s) for submission
(h) References

ii) The Pub Exec committee will review all proposals to verify use of the correct proposal format and to determine if there is specific overlap with another paper or abstract in process, related to either the same outcome (such as cardiovascular endpoints) or to the same CRIC biochemical/demographic/clinical factor. In cases of such overlap, the proposer will be encouraged to collaborate with the existing writing committee. Approved manuscript proposals will be posted on the secure portion of the CRIC web site. In addition, the Pub Exec committee will categorize the proposal as seeking to produce one of the two types of CRIC manuscripts described below.

iii) Investigators with (or submitting) ancillary grants that address or supplement core domains of science will be informed that the default approach will be for core CRIC investigators to lead proposals/publications highlighting the core measures, unless permission is specifically granted from the Pub Exec committee for the ancillary investigator to initially report these findings. Under the default approach, ancillary investigators could incorporate the core measures as adjustment factors (or primary predictors insomuch that copyright isn't infringed upon) and not report out the primary associations with these data.

iv) Upon approval by the Pub Exec committee, the SDCC will assign a manuscript number to the proposal and log it into a tracking system. After approving the manuscript, the Pub Exec committee will name the Writing Committee Chair and constitute a Writing Committee, considering any recommendations from the Clinical Center PIs, and the designated Writing Committee Chair, as described below.

v) The Pub Exec committee, in consultation with the SDCC, will determine priorities for data analyses for manuscripts and abstracts that will occur at the SDCC. However, preparation of manuscripts for which the data analyses do not occur at the SDCC may start as soon as the Pub Exec committee approves and the SDCC is able to provide the data resources needed for analysis. All manuscripts for which the data analyses are done locally may be subject to analysis verification by the SDCC Biostatistics Analysis Center (BAC) prior to submission to a journal (see below and the attached SOP for additional details).

vi) Any investigator submitting a manuscript proposal must agree to the CRIC internal data sharing policy, below. By signing the signature page of this publications policy, the investigator confirms receipt of and commitment to this data sharing policy:

I agree to the following conditions regarding the use and disclosure of any CRIC Study data I receive from the CRIC Scientific and Data Coordinating Center:

(1) I will not use or further disclose CRIC data for any purpose other than accomplishing the approved scientific aims for which I will be conducting analyses.

(2) I will abide by all requirements of the CRIC Publications and CRIC Ancillary Studies policies with regard to the use and disclosure of any CRIC data.

(3) I will implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality and integrity of any CRIC data as well as prevent its inadvertent use or disclosure.

(4) I agree to return or destroy any CRIC data I receive upon completion of analysis (e.g., defined by the acceptance of the manuscript reporting your findings) or at the end of any mandatory period of data archiving at my institution.

vii) The SDCC will maintain records indicating the distribution of authorship by individual and location.

B. Types of Manuscripts

There are two manuscript types, **Core Study Manuscripts** and **Ancillary Study Manuscripts**. Definitions of these are below. Analyses occur either centrally (at the SDCC) or locally (at a clinical or reading center) with consideration for the request of proposing investigators, and at the discretion of the Pub Exec committee in close consultation with the SDCC.

(1) The Pub Exec committee will review all study paper proposals and may nominate additional coauthors, regardless of whether analysis occurs centrally or locally.

(2) The Pub Exec committee will monitor both centrally and locally analyzed papers for progress. In general, all papers will be subject to a verification of analyses by the SDCC before submission to a journal. In specific instances, with approval from the Publications Committee and SDCC, a paper may be published without verification of analyses. In such cases, the authors must submit the paper with a disclaimer indicating that the CRIC Study does not certify the analyses.

ii) Core Study Manuscripts

(1) Core Study Manuscripts analyze data collected as part of the Core CRIC data set, and directly derive from the CRIC Core study aims as described in the CRIC Study Protocol. The Core CRIC data set consists of all data collected as part of the CRIC Study annual awards from the NIH to the SDCC and Clinical Centers, data collected through NIH-funded supplements to these awards, and data collected through other supplemental funding to the CRIC Study (e.g. funding from industry). In addition, it is recognized (see the CRIC Ancillary Study Policy) that data collected under the auspices of a formally approved CRIC Ancillary Study will become part of the Core CRIC data set once collected and their analysis related to the Ancillary Study aims has been completed.

(2) The Pub Exec committee will develop a proposed list of Core Manuscripts that should be developed based on Core CRIC data and Core CRIC Study aims. The Domain SCs are one mechanism that will be utilized for this purpose. This list will be subject to review and approval by the Publications Committee. The Pub-

Exec committee will maintain the approved list of Core Manuscripts, and will coordinate initiation of Writing Committees with the SDCC to develop these manuscripts.

iii) Ancillary Study Manuscripts

(1) Ancillary Study Manuscripts will be based, in part, on data elements originating from the specific aims of approved ancillary studies, regardless of the type of award. These new data elements derive directly from participants or from previously collected samples, images, or other sources (e.g., medical records). Examples of studies that may lead to Ancillary Study Manuscripts are investigator-initiated NIH research awards (R01s), grants from academic institutions, grants from private sources (e.g., drug companies), training grants (some K-series awards), or those performed at no cost (generally because of the special interest of a researcher).

(2) Supplemental data made possible by funding that is awarded to "the CRIC Study" (e.g. in the form of industry grants) rather than to an individual investigator will be considered, "core CRIC data."

(3) Analyses will be performed by the ancillary study investigators or at the SDCC if funds are allocated to the SDCC for that purpose. Ancillary studies are subject to the same review and tracking procedures as Core Manuscripts.

(4) Ancillary Study Manuscripts will be tracked centrally for progress in the same way that all Core Manuscripts will be tracked and will undergo a verification of analyses by the SDCC before submission to a journal.

C. Changes in Scope of Approved Manuscripts

i) Changes in the Specific Aims – If a writing committee decides that a change in the approved specific aims for a manuscript is warranted, the writing committee chair will communicate this along with a brief rationale to the Pub Exec committee for its approval.

ii) Development of More Than One Manuscript from a Single Proposal - If initial analyses suggest that a proposal should be split into two manuscripts, the rationale for this split should be submitted by the writing committee chair to the Pub Exec committee for their approval. In general, the writing committee members will remain be the same for both papers. A revised version of the proposal specifically outlining the content of the second manuscript should be submitted to the Pub Exec committee for review and approval. A new manuscript number will be assigned to this version to distinguish it from the original proposal.

iii) Withdrawal of Plans to Complete an Approved Manuscript - Under the circumstance where a writing committee reaches a conclusion that it will not produce a manuscript, or where it will combine its analyses with those of another writing committee for the purpose of generating one integrated manuscript, the writing committee chair(s) will submit the rationale for these changes to the Pub Exec committee for their approval. Withdrawn proposals will be noted as "Inactive" in the publications tracking database.

II. Formation of Writing Committees

A. Designation of Writing Committee Chairs will be based largely on manuscript proposal submission. The author of the proposal will generally be considered to be the Writing

Committee chair for that particular manuscript. While the following principles apply to both types of CRIC Study manuscripts, ordinarily, the individual proposing a Core Manuscript and the principal investigator of a CRIC ancillary study will serve as the Writing Committee Chairs for these two types of manuscripts, respectively.

B. The Pub Exec committee will provide oversight in the process of convening Writing Committees. The publications project management liaison will receive nominations for members of writing committees from CRIC Investigators before proposing a writing committee to the full Pub Exec committee. Selection of a Chair of a Writing Committee will require seven of nine affirmative votes from the CRIC Steering Committee members.
   i) The Pub Exec committee will consider the following principles when selecting Writing Committee members:
      (1) Equitable access to leadership of Writing Committees as delineated in Section I. Publication Policy Principles.
      (2) Expertise of proposed Writing Committee member based on prior publications and interest as demonstrated through ancillary study proposals, etc.
      (3) Proposed Writing Committee member's available time and commitment to moving manuscript development forward.
      (4) Writing committees may range in membership but will generally be limited to 15 members. To assist in selection when more than 15 members are identified, a priority ranking can be used as follows: first – *CRIC PIs*, second – *CRIC Core Investigators*, and third – *CRIC Team Members*. This limitation is only a rough guide and the Pub-Exec SC need not adhere to it explicitly if there are other considerations specified in this policy that dictate otherwise or if circumstances particular to the writing committee require flexibility.
      (5) *CRIC Team Members* who seek and receive ancillary funding from career development/training awards based on work with the CRIC Study (e.g., some K-series NIH awards) that do not provide funding to generate ancillary data for CRIC (outside of core CRIC data elements) may be limited to chairing one Writing Committee addressing the science described in their career development award. However, the Publications Committee need not adhere to this guideline when the contributions of the *CRIC Team Member* are deemed sufficient to warrant more than one Writing Committee Chair assignment. In addition, this guideline will not apply when a *CRIC Team Member* with career development or training award is identified by a CRIC PI to be a *CRIC Core Investigator*.

C. General Principles for the Selection of Writing Committees:
   i) The principles for selection of Writing Committees recognize that the CRIC Study will generate many manuscripts.
   ii) The development of the CRIC Study aims dictated a large number of Core Manuscripts, for which a broad constituency of *CRIC Investigators* will have interest in authorship.
   iii) Publications arising from training grant ancillaries (e.g., K01, K23, etc.) require special consideration because of their limited resources and the particular needs of trainees to be academically productive during their training.
   iv) The Pub Exec committee will be responsible for the development and maintenance of a working list of expected CRIC manuscripts and the designation of writing

committees with input from the SDCC about availability of data for required analyses.

v) To assist in selection of writing committee members when more candidates are identified than can be accommodated, a priority ranking can be used as follows: first – *CRIC PIs*, second – *CRIC Core Investigators*, and third – *CRIC Team Members*. This priority ranking only is meant to be a rough guide. For example, writing committees for Core Manuscripts and Ancillary Manuscripts will often include individuals who have collaborated on the development of these manuscript ideas.

vi) The Writing Committee Chair, in collaboration with the Pub Exec committee, will work to identify potential writing committee members from among interested *CRIC Investigators* and *Ancillary Study Investigators*. It is anticipated that for Investigator Initiated Manuscripts and Ancillary Manuscripts, that the Writing Committee Chair will take the lead on nominating individuals to serve on the writing committee. In all cases, the composition of these committees will be approved by the Pub Exec committee. Nomination to serve on a writing committee does not guarantee co-authorship. At least one member of the SDCC will have membership on each writing committee and a liaison from the SDCC will work with each writing committee to facilitate the process and interactions with the SDCC.

vii) Writing Committee participation should also be based on the contributions made by an individual to the conception and design of the manuscript proposal, the acquisition of data, the expected role in analysis and interpretation of data, the initial development or subsequent editing of the manuscript, and final approval of the version to be published. Other potential contributors not expected to meet these requirements should be included in the acknowledgements section as appropriate for the degree to which they contributed to the work reported in the manuscript.

D. Principles for formation of writing committees for both types of CRIC manuscripts: Outlined below is a selection procedure for membership in writing groups. The goals of writing group selection include balanced involvement in writing activities by CRIC investigators, widespread representation of CRIC Clinical Centers whenever appropriate and feasible, and inclusion of content-area experts throughout the CRIC research network. To achieve these goals, the following steps are outlined:

i) Once a core manuscript proposal has been approved by the Pub Exec committee, the SDCC will send an email to all CRIC core and ancillary investigators, study coordinators and reading center consultants to solicit interest in being included in the writing group, from individuals who were not already nominated by the manuscript proposal convener.

(1) For core CRIC manuscripts, opportunities for authorship will be open to all CRIC PIs, CRIC Core Investigators, and CRIC Team Members, as well as to qualifying ancillary investigators (see V.D.ii.2, below) who identify their intention to fulfill the criteria for authorship in the Uniform Requirements (see page 14, below).

ii) Once an ancillary manuscript proposal has been approved by the Pub Exec committee, the SDCC will send an email to all CRIC core and ancillary investigators, study coordinators, and reading center consultants who were not already nominated by the manuscript proposal convener to solicit interest in being included in the writing group.

(1) For ancillary manuscripts, opportunities for authorship will be open to all CRIC PIs, CRIC Core Investigators, and CRIC Team Members, based at Clinical Centers participating in data collection for the related ancillary study, as well as to other qualifying investigators (see V.D.ii.2, below) who identify their intention to fulfill the criteria for authorship in the Uniform Requirements (see page 14, below).
(2) CRIC PIs, CRIC Core Investigators, and CRIC Team Members based at Clinical Centers **not** participating in relevant ancillary data collection (for ancillary manuscripts) as well as ancillary investigators (for ancillary and core manuscripts) will qualify to request authorship upon providing sufficient documentation of expertise and interest in the topic area of the manuscript in addition to their intention to fulfill the criteria for authorship in the Uniform Requirements (see page 14, below).
(3) Nominees for authorship will send this documentation to the SDCC for consideration by the Pub Exec committee.

iii) Core CRIC investigators at CRIC's 7 Clinical Centers will be asked to submit their statements of interest to the PI at their Center. The Clinical Center PI will then be asked to review all such statements at their site, and send a prioritized list of investigators to potentially be included on the manuscript, to the SDCC within 1 week after the date of the email solicitation for writing group membership. If this list includes more than one nominee, the PI is asked to provide a justification for the inclusion of multiple authors from their Clinical Center.

iv) All interested investigators will be instructed to include the following in their statements:
(1) Acknowledgment of availability to adhere to timelines outlined in the Publications Policy, and
(2) Their level of interest in the manuscript (on a scale from 1 to 5, with 1 being the highest interest)
(3) Any additional relevant information regarding particular experience in the content area (this will not be a prerequisite for inclusion on writing committees).
(4) How they will fulfill sufficient criteria to warrant authorship as outlined in the Uniform Requirements (see Section V.E.ii.1. and page 14, below).

v) Ancillary investigators, who are not core CRIC investigators, will be asked to submit their statements, including all requested elements above, directly to the SDCC for submission to the Pub-Exec Committee.

vi) After one week has elapsed, all nominations will be compiled and presented to the Pub Exec committee for deliberation and decision-making. Inclusion in the writing group will depend principally on representation of Centers, equitable distribution of writing assignments across individuals, and the anticipated size of the committee that will be acceptable to the journals that are the likely target for submission. In addition, particular levels of expressed interest or experience with the content area will be considered.

vii) Principles to be used by the Pub Exec committee to guide achievement of adequate representation of CRIC core and ancillary investigators in writing groups:
(1) For CRIC Study papers **not** directly addressing a specific aim from an ancillary study, representation if possible, of all 9 CRIC entities with voting rights (7

Clinical Centers, the NIH, and the SDCC), at which individuals indicate an interest and commitment.

(2) For CRIC Study papers directly addressing a specific aim from an ancillary study, representation, if possible, of all clinical sites involved in data collection for an ancillary study, the NIH, and the SDCC, at which individuals indicate an interest and commitment.

(3) Inclusion of representatives from Reading Centers, when appropriate.

(4) Conveners of manuscripts may propose inclusion of non-CRIC researchers who bring particular expertise in a topic.

(a) Basis for inclusion will need to be clearly stated.

(5) Pub Exec committee will consider these potential authors, respecting the primary goals of the writing selection process.

(6) Multiple roles and a broad scope of activities related to a manuscript by investigators at one or more Clinical Center or the SDCC will often justify multiple authors from those centers.

viii) Writing committee rosters endorsed by the Pub Exec committee will be circulated to the Steering Committee voting members, who will have one week to provide comments or feedback.

ix) The entire process described above will typically take place during the period of one month following the approval of any manuscript proposal by the Pub Exec committee.

x) CRIC-wide authorship by each CRIC entity (SDCC, Clinical Centers (with coordinator representation), Reading Centers, Laboratories, NIDDK) will be reviewed at least three times per year and presented to the Steering Committee.

E. Writing Committee Responsibilities

i) Writing Committee Chair

(1) The Writing Committee Chair is responsible for all phases of manuscript preparation including:

(a) Preparation of the manuscript proposal, the identification of data analyses needed, and submission of interim status reports to the Pub Exec committee;

(b) Assignment of tasks to writing committee members with clear deadlines for completion of these tasks and determination that the tasks are completed on schedule;

(c) Preparation and circulation of drafts for approval by each member of the writing committee before submission of a penultimate draft to the Pub Exec committee and before submission to a journal;

(d) Determination of the order of authorship on the manuscript. A major criterion will be the effort and contribution made by each member of the writing committee in the preparation of the manuscript as defined in the Uniform Requirements;

(e) Selection of a journal to which the manuscript will be submitted;

(f) Correspondence with co-authors, communication with the SDCC and the Pub Exec committee, responses to the Pub Exec committee and NIDDK reviews, and to journal editors.

(2) Writing Committee chairs should contact each member of the writing committee to discuss the outline of the paper, data analysis plan, and the responsibilities and assignments for each member.

ii) Writing Committee Members

(1) Individuals selected for a writing committee will be reminded of the criteria from the Uniform Requirements they have agreed to fulfill and will be held accountable for doing so as the writing activities progress. All members of writing committees will be required to participate in writing committee activities and be able to confirm that they:

(a) gave final approval of the submitted manuscript.

(b) participated sufficiently in the work to take public responsibility for its content.

(c) made substantial contributions to the intellectual content of the paper through:

(i) conception and design of the work, OR acquisition of data, OR analysis and interpretation of data,

AND

(ii) drafting OR critical revision of the manuscript for important intellectual content,

AND

(iii) statistical analysis, OR obtaining funding, OR administrative or technical support, OR supervision.

(2) Members are responsible for performance of tasks assigned by the Chair within the allotted time.

(3) Each member must participate actively in the preparation of the manuscript and meet the criteria defined in the Uniform Requirements and in Section V.E.ii.1, above.

(a) If a writing committee member does not accomplish the tasks assigned to him/her and has not contributed to the manuscript, he/she may be removed from the writing committee.

(b) Prior to a request for removal of any writing committee member, the Chair must contact the member in writing with a request for participation or performance of a task, and indicate that non-response within two weeks will be considered notice that the writing committee member no longer wishes to participate in the writing activity.

(c) The chairperson must then send a letter to the Pub Exec committee requesting the removal from the writing committee of non-contributing members. All efforts should be made by the writing committee chair to reconcile the views of all parties. Recommendations to remove a writing committee member must be approved by the Executive Committee.

(4) All authors who do not meet the criteria for authorship should be acknowledged separately in the acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, general supervision of a research group, assistance in obtaining funding, writing assistance, or a department chair who provided only general support.

(5) Final order of authors to be listed on a submitted manuscript approved by the Pub Exec committee will be established by the Chair after consideration of each writing committee member's role in preparation of the manuscript. Special recognition should be given to the authorship position of the biostatisticians as they play an essential role in statistical analyses supporting manuscripts.

III. Schedule for Manuscript Preparation

A. Draft
   i) It is ordinarily expected that writing committees will complete a first draft within two (2) months after receipt of a set of complete analyses from the SDCC.
      (1) A first draft will consist, at a minimum, of Introduction, Methods, and Results Sections.
   ii) The Writing Committee Chair should send this draft to the members of the writing committee. It is recommended that a response deadline of 2 (two) weeks be given to writing committee members to prevent unnecessary delays.

B. Penultimate Draft
   i) The penultimate draft becomes due three (3) to four (4) months after the first draft is distributed to the writing committee.
   ii) The penultimate draft should include:
      (1) A title with the acronym "CRIC," whenever possible.
      (2) "and the CRIC Study Investigators" as part of the list of author list, with a footnote to the specific individuals included in this group (the CRIC Steering Committee voting members). Description of the grants (and grant numbers) as an acknowledgement. This will ordinarily include grants to the SDCC, to all clinical centers whose data were included, and any other relevant grant (e.g., CTRCs)
   iii) A penultimate draft should be sufficiently complete for submission to a journal. After review and approval of the penultimate draft by writing committee members, the writing committee should send the penultimate draft the Pub Exec committee with a cover letter stating that this penultimate draft is ready for review. This letter should also include:
      (1) An explicit statement from the Writing Committee chair confirming that the manuscript is consistent with the scope reflected in the originally approved manuscript proposal. If the manuscript is not consistent with this scope an explanation for this must be provided. The Pub Exec committee will then review the scope approved in the original manuscript proposal to ensure that it is consistent with the current submission.
      (2) An explicit statement describing the grants (and grant numbers) that are acknowledged in the body of the draft manuscript
   iv) The penultimate draft of the manuscript should also be submitted to the SDCC biostatisticians for data analysis verification (see below and attached SOP for additional details).

C. Review (see attached SOP for additional details)
   i) The CRIC Pub Exec committee, the SDCC biostatistical group, and the CRIC Steering Committee voting members (the individuals included in the "and the CRIC Study Investigators" author list) will be given access to the penultimate draft manuscript for approval prior to submission to the journal. Members of the Pub Exec

committee and the Steering Committee voting members will be given one week to provide feedback/comments, which will be provided to the Writing Committee chair who will decide if this input should lead to modification in the draft manuscript prior to submission. If Steering Committee voting members do not have specific feedback/comments on the manuscript, they must formally indicate to the SDCC Pub Exec project manager that the manuscript was reviewed and is approved for submission. The time line given to the SDCC biostatisticians will vary depending on the complexity of the data verification, but at least two weeks should be allowed for this step.

D. Verification (see attached SOP for additional details)
   i) The SDCC will initiate verification (independent replication of the analysis data set and results) of the manuscript results for data sets analyzed both at the SDCC as well as by outside analytical teams. This will occur simultaneously with the Pub Exec review of the penultimate draft of the manuscript and is required prior to submission to a journal.
      (1) Verification of data sets will be conducted according to the scope, aims, and hypotheses outlined in the approved manuscript. Changes to any of the elements should be approved by Pub Exec prior to the submission of the penultimate manuscript version.
         (i) Verification of data sets analyzed by the SDCC as well as by outside analytical teams will include the insertion of the appropriate acknowledgements of CRIC components and sponsoring agencies

      In selected instances, when appropriate arrangements have been made with the SDCC, verification will not be required, and the publication will appear with a disclaimer from the CRIC study to that effect.
      (2) For data sets analyzed by outside analytical teams, when a manuscript is ready for submission, the writing committee chair should submit the following documents at the same time that the manuscript is submitted for Pub Exec review:
         (a) Summary of analysis, including:
            (i) Details on how to derive the final data set from the data set provided by the SDCC, including added variables, deleted records, and changed data elements (e.g., out of range values set to missing).
            (ii) Definitions for all derived variables, including information on handling missing values.
            (iii) The data set used, variables used (with variable names in the order that they appear), sample size and statistical methods for each table, figure, and numerical or statistical claim in the text.
            (iv) Sample code for all statistical methods. For example, when two groups were compared, provide SAS (or STATA) code for calculating the p values. For models, provide code for the model. If there are multiple p values provided for the same statistical procedure, specify which p values were used.
            (v) Note that the explanations in this summary should be clear and sufficiently detailed for another analyst to replicate all analysis accordingly. Unclear explanation may lead to delays in the completion of verification analysis.
         (b) Final data set(s):

(i) All variables should be labeled.
(ii) Formats should be provided for all categorical variables.

(c) Analytical programs that were used to generate all numbers that appear in the text, figures, and tables or support statistical claims.

(d) The manuscript to be submitted, including all tables, figures, and appendices, and supplemental tables.

(3) Depending on the extent and complexity of analysis, the verification analysis can take at least two weeks from the day of submission to the SDCC. More time may be required depending on the complexity of the analysis.

E. Submission to a Journal
   i) The manuscript should be submitted to a journal immediately after final sign off.
   ii) The Pub Exec committee, the SDCC, and all co-authors must receive a copy of the journal cover letter and final draft of the manuscript.
   iii) Once the manuscript is accepted by a journal and the galley proofs are generated, the galley proofs should be submitted to Pub Exec along with talking points and/or a lay summary of the manuscript suitable for use in the event that interviews and/or press releases related to the manuscript take place or for posting on the CRIC website.

F. Verification of Resubmissions to a Journal
   i) Often a manuscript needs to be revised for submission to the same journal or a different journal. If additional analysis is required for the revision, another verification analysis may be performed following the steps mentioned above.

G. Publication
   i) When a manuscript is accepted for publication, the galley proof may be reviewed and verified by the analytical team at SDCC.

H. Post-publication
   i) In the event that data problems, such as incorrect derivation of a variable, are found after the manuscript is published, clear and timely communication should be made between the SDCC and the writing committee chair.

I. Deviations from Schedule
   i) Deviation from this schedule requires approval from the Pub Exec committee.
   ii) Failure to adhere to this schedule will prompt a review of circumstances.
   iii) If it is determined that a manuscript is delinquent, this could be the basis for replacing the member(s) of the writing committee responsible for the delay, or for disbanding or reconstituting the writing committee.

J. Tracking Manuscripts
   i) The Writing Committee Chair must keep the Pub Exec committee and the co-authors informed as to the manuscript's progress through journal review.
   ii) Upon publication of the manuscript, the Writing Committee Chair must provide either a reprint or copies of the final publication to the Pub-Exec committee.
   iii) The Writing Committee Chair must also send a copy of the journal's letter of acceptance, request for revisions, or letter of rejection to the Pub Exec committee.

K. If there are substantive changes (adding new data or re-analyzing the existing data set used for the initial submission) made in the manuscript during journal review (major findings or conclusions, alterations of the sample, exclusion/inclusion of major covariates), the revised manuscript should be submitted to the Pub Exec committee for

re-review.

IV. **Abstracts and Presentations**

A. Preparation and Submission of Abstracts for Scientific Meetings

i) No abstracts may be submitted to any national or international organization for consideration without prior review and approval by the CRIC Pub Exec committee, and sign-off from all included co-authors.

ii) Proposals for CRIC abstracts requiring data analyses must be approved before the SDCC can honor specific data requests.

iii) The SDCC requires at least four weeks to prepare data for use in proposed abstracts or presentations.

iv) An investigator who submits an abstract without these approvals may be asked to withdraw the abstract or presentation in question.

v) It is the intention of this policy to promote the conversion of as many abstracts as possible into full manuscripts. Abstracts should be submitted for review and approval utilizing the Manuscript Proposal Review template.

vi) If a Writing Committee has been assembled previously, it is encouraged that all writing committee members be identified as an author of that abstract, whenever possible.

(1) It is recognized that time and space constraints may preclude the inclusion of all approved writing committee members as authors on an abstract.

(2) Writing committee chairs are encouraged to include as many co-authors as can be accommodated and whose approval for the submitted work can be obtained prior to established deadlines for the abstract.

(3) Any co-author who has not approved of the content of the abstract should not be included in the final list of authors for the abstract.

(4) In the special circumstance where a writing committee chair has received permission from contributing authors, an abstract may be submitted listing only the writing committee chair and the corporate CRIC authorship.

vii) The full text of abstracts is due to the Pub Exec committee for review no less than two weeks before the abstract submission deadline. Abstracts submitted too late for review may not be approved for submission if the Pub Exec committee is not able to approve in time.

B. **Principles and Guidelines For CRIC Presentations**

i) The following guidelines apply to all presentations including poster presentations, oral communications at national meetings, grand rounds, invited presentations, press releases and interviews, and talks to community physicians, etc. that include CRIC data:

(1) Presenters are encouraged to freely present <u>published</u> material from CRIC.

(2) Presenters are encouraged to freely present CRIC data that has appeared in publications or in abstract form at national meetings with appropriate acknowledgements.

(3) Distribution of written handout material containing CRIC data that have <u>not</u> been published is prohibited.

(4) Presenters who have questions about unpublished material that they would like to present must seek approval from the CRIC Steering Committee (not the Pub-Exec SC).
(5) Presentation of ancillary data from CRIC must adhere to these guidelines.
(6) Slide presentations given for regional, national and international audiences will be made available on the CRIC internal website.
(7) If available, the interview questions should be submitted to the Pub Exec committee for review prior to the interview. In addition, prepared responses, in the form of talking points and/or lay summaries of the manuscripts, should be submitted and approved by the Pub Exec committee prior to the interview.
(8) Press releases prepared by a journal or society related to a published manuscript must be reviewed by the Pub Exec committee prior to release

C. Accepted Abstracts and Invited Presentations
   i) Copies of accepted abstracts or invited presentations (including tables and graphs) must be submitted to the Pub Exec committee.

Uniform Requirements for Manuscripts Submitted to Biomedical Journals

Updated October 2008

Publication Ethics: Sponsorship, Authorship, and Accountability

International Committee of Medical Journal Editors (see end of text)

A small group of editors of general medical journals met informally in Vancouver, British Columbia, in 1978 to establish guidelines for the format of manuscripts submitted to their journals. This group became known as the Vancouver Group. Its requirements for manuscripts, including formats for bibliographic references developed by the National Library of Medicine (NLM), were first published in 1979. The Vancouver Group expanded and evolved into the International Committee of Medical Journal Editors (ICMJE), which meets annually. The ICMJE has gradually broadened its concerns to include ethical principles related to publication in biomedical journals.

The ICJME has produced multiple editions of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Over the years, issues have arisen that go beyond manuscript preparation, resulting in the development of a number of Separate Statements on editorial policy. The entire Uniform Requirements document was revised in 1997; sections were updated in May 1999 and May 2000. In May 2001, the ICMJE revised the sections related to potential conflict of interest. In 2003, the committee revised and reorganized the entire document and incorporated the Separate Statements into the text. The committee prepared this revision in 2008.

The total content of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals may be reproduced for educational, not-for-profit purposes without regard for copyright; the committee encourages distribution of the material.

Journals that agree to use the Uniform Requirements are encouraged to state in their instructions to authors that their requirements are in accordance with the Uniform Requirements and to cite this version. Journals that wish to be listed on www.ICMJE.org as a publication that follows the Uniform Requirements should contact the ICMJE secretariat office.

The ICMJE is a small working group of general medical journals, not an open-membership organization. Occasionally, the ICMJE will invite a new member or guest when the committee feels that the journal or organization will provide a new perspective. Open membership organizations for editors and others in biomedical publication include the World Association of Medical Editors www.WAME.org and the Council of Science Editors www.councilofscienceeditors.

I.B. Potential Users of the Uniform Requirements

The ICMJE created the Uniform Requirements primarily to help authors and editors in their mutual task of creating and distributing accurate, clear, easily accessible reports of biomedical studies. The initial sections address the ethical principles related to the process of evaluating,

improving, and publishing manuscripts in biomedical journals and the relationships among editors and authors, peer reviewers, and the media. The latter sections address the more technical aspects of preparing and submitting manuscripts. The ICMJE believes that the entire document is relevant to the concerns of both authors and editors.

The Uniform Requirements can provide many other stakeholders—peer reviewers, publishers, the media, patients and their families, and general readers—with useful insights into the biomedical authoring and editing process.

I. C. How to Use the Uniform Requirements

The Uniform Requirements state the ethical principles in the conduct and reporting of research and provide recommendations relating to specific elements of editing and writing. These recommendations are based largely on the shared experience of a moderate number of editors and authors, collected over many years, rather than on the results of methodical, planned investigation that aspires to be "evidence-based." Wherever possible, recommendations are accompanied by a rationale that justifies them; as such, the document serves an educational purpose.

Authors will find it helpful to follow the recommendations in this document whenever possible because, as described in the explanations, doing so improves the quality and clarity of reporting in manuscripts submitted to any journal, as well as the ease of editing. At the same time, every journal has editorial requirements uniquely suited to its purposes. Authors therefore need to become familiar with the Instructions to Authors specific to the journal they have chosen for their manuscript—for example, the topics suitable for that journal, and the types of papers that may be submitted (for example, original articles, reviews, or case reports)—and should follow those instructions.

II. Ethical Considerations in the Conduct and Reporting of Research

II.A Authorship and Contributorship

II.A.1. Byline Authors

An "author" is generally considered to be someone who has made substantive intellectual contributions to a published study, and biomedical authorship continues to have important academic, social, and financial implications (1). In the past, readers were rarely provided with information about contributions to studies from persons listed as authors and in Acknowledgments (2). Some journals now request and publish information about the contributions of each person named as having participated in a submitted study, at least for original research. Editors are strongly encouraged to develop and implement a contributorship policy, as well as a policy on identifying who is responsible for the integrity of the work as a whole.

While contributorship and guarantorship policies obviously remove much of the ambiguity surrounding contributions, they leave unresolved the question of the quantity and quality of contribution that qualify for authorship. The ICJME has recommended the following criteria for

authorship; these criteria are still appropriate for journals that distinguish authors from other contributors.

- Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.

- When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript (3). These individuals should fully meet the criteria for authorship/contributorship defined above and editors will ask these individuals to complete journal-specific author and conflict-of-interest disclosure forms. When submitting a manuscript authored by a group, the corresponding author should clearly indicate the preferred citation and identify all individual authors as well as the group name. Journals generally list other members of the group in the Acknowledgments. The NLM indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript; it also lists the names of collaborators if they are listed in Acknowledgments.

- Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.

- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.

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

Some journals now also request that one or more authors, referred to as "guarantors," be identified as the persons who take responsibility for the integrity of the work as a whole, from inception to published article, and publish that information.

Increasingly, authorship of multicenter trials is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for authorship/contributorship.

The group should jointly make decisions about contributors/authors before submitting the manuscript for publication. The corresponding author/guarantor should be prepared to explain the presence and order of these individuals. It is not the role of editors to make authorship/contributorship decisions or to arbitrate conflicts related to authorship.

II.A.2. Contributors Listed in Acknowledgments

All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support. Editors should ask corresponding authors to declare whether they had assistance with study design, data collection, data analysis, or manuscript preparation. If such assistance was available, the authors should disclose the identity of the individuals who provided this

assistance and the entity that supported it in the published article. Financial and material support should also be acknowledged.

Groups of persons who have contributed materially to the paper but whose contributions do not justify authorship may be listed under such headings as “clinical investigators” or “participating investigators,” and their function or contribution should be described—for example, “served as scientific advisors,” “critically reviewed the study proposal,” “collected data,” or “provided and cared for study patients.” Because readers may infer their endorsement of the data and conclusions, these persons must give written permission to be acknowledged.

II.B Editorship

II.B.1. The Role of the Editor

The editor of a journal is the person responsible for its entire content. Owners and editors of medical journals have a common endeavor—publication of a reliable, readable journal produced with due respect for the stated aims of the journal and for costs. Owners and editors, however, have different functions. Owners have the right to appoint and dismiss editors and to make important business decisions in which editors should be involved to the fullest extent possible. Editors must have full authority for determining the editorial content of the journal. The concept of editorial freedom should be resolutely defended by editors even to the extent of their placing their positions at stake. To secure this freedom in practice, the editor should have direct access to the highest level of ownership, not to a delegated manager.

Editors of medical journals should have a contract that clearly states his or her rights and duties, the general terms of the appointment, and the mechanisms for resolving conflict.

An independent editorial advisory board may be useful in helping the editor establish and maintain editorial policy.

II.B.2. Editorial Freedom

The ICMJE adopts the World Association of Medical Editors’ definition of editorial freedom. According to this definition, editorial freedom, or independence, is the concept that editors-in-chief have full authority over the editorial content of their journal and the timing of publication of that content. Journal owners should not interfere in the evaluation, selection, or editing of individual articles either directly or by creating an environment that strongly influences decisions. Editors should base decisions on the validity of the work and its importance to the journal’s readers not on the commercial success of the journal. Editors should be free to express critical but responsible views about all aspects of medicine without fear of retribution, even if these views conflict with the commercial goals of the publisher. Editors and editors’ organizations have the obligation to support the concept of editorial freedom and to draw major transgressions of such freedom to the attention of the international medical, academic, and lay communities.

II.C. Peer Review

Unbiased, independent, critical assessment is an intrinsic part of all scholarly work, including the scientific process. Peer review is the critical assessment of manuscripts submitted to journals by

experts who are not part of the editorial staff. Peer review can therefore be viewed as an important extension of the scientific process. Although its actual value has been little studied and is widely debated (4), peer review helps editors decide which manuscripts are suitable for their journals and helps authors and editors to improve the quality of reporting. A peer-reviewed journal submits most of its published research articles for outside review. The number and kinds of manuscripts sent for review, the number of reviewers, the reviewing procedures, and the use made of the reviewers' opinions may vary. In the interests of transparency, each journal should publicly disclose its policies in its Instructions to Authors.

II.D. Conflicts of Interest

Public trust in the peer-review process and the credibility of published articles depend in part on how well conflict of interest is handled during writing, peer review, and editorial decision making. Conflict of interest exists when an author (or the author's institution), reviewer, or editor has financial or personal relationships that inappropriately influence (bias) his or her actions (such relationships are also known as dual commitments, competing interests, or competing loyalties). These relationships vary from negligible to great potential for influencing judgment. Not all relationships represent true conflict of interest. On the other hand, the potential for conflict of interest can exist regardless of whether an individual believes that the relationship affects his or her scientific judgment. Financial relationships (such as employment, consultancies, stock ownership, honoraria, and paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself. However, conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion.

All participants in the peer-review and publication process must disclose all relationships that could be viewed as potential conflicts of interest. Disclosure of such relationships is also important in connection with editorials and review articles, because it can be more difficult to detect bias in these types of publications than in reports of original research. Editors may use information disclosed in conflict-of-interest and financial-interest statements as a basis for editorial decisions. Editors should publish this information if they believe it is important in judging the manuscript.

II.D.1. Potential Conflicts of Interest Related to Individual Authors' Commitments

When authors submit a manuscript, whether an article or a letter, they are responsible for disclosing all financial and personal relationships that might bias their work. To prevent ambiguity, authors must state explicitly whether potential conflicts do or do not exist. Authors should do so in the manuscript on a conflict-of-interest notification page that follows the title page, providing additional detail, if necessary, in a cover letter that accompanies the manuscript. *(See Section IV. A. 3. Conflict-of-Interest Notification Page)*

Authors should identify Individuals who provide writing or other assistance and disclose the funding source for this assistance.

Investigators must disclose potential conflicts to study participants and should state in the manuscript whether they have done so.

Editors also need to decide whether to publish information disclosed by authors about potential conflicts. If doubt exists, it is best to err on the side of publication.

II.D.2. Potential Conflicts of Interest Related to Project Support

Increasingly, individual studies receive funding from commercial firms, private foundations, and government. The conditions of this funding have the potential to bias and otherwise discredit the research.

Scientists have an ethical obligation to submit creditable research results for publication. Moreover, as the persons directly responsible for their work, researchers should not enter into agreements that interfere with their access to the data and their ability to analyze them independently, and to prepare and publish manuscripts. Authors should describe the role of the study sponsor, if any, in study design; collection, analysis, and interpretation of data; writing the report; and the decision to submit the report for publication. If the supporting source had no such involvement, the authors should so state. Biases potentially introduced when sponsors are directly involved in research are analogous to methodological biases. Some journals, therefore, choose to include information in the Methods section about the sponsor's involvement.

Editors may request that authors of a study funded by an agency with a proprietary or financial interest in the outcome sign a statement, such as "I had full access to all of the data in this study and I take complete responsibility for the integrity of the data and the accuracy of the data analysis." Editors should be encouraged to review copies of the protocol and/or contracts associated with project-specific studies before accepting such studies for publication. Editors may choose not to consider an article if a sponsor has asserted control over the authors' right to publish.

II.D.3. Potential Conflicts of Interest Related to Commitments of Editors, Journal Staff, or Reviewers

Editors should avoid selecting external peer reviewers with obvious potential conflicts of interest--for example, those who work in the same department or institution as any of the authors. Authors often provide editors with the names of persons they feel should not be asked to review a manuscript because of potential, usually professional, conflicts of interest. When possible, authors should be asked to explain or justify their concerns; that information is important to editors in deciding whether to honor such requests.

Reviewers must disclose to editors any conflicts of interest that could bias their opinions of the manuscript, and they should recuse themselves from reviewing specific manuscripts if the potential for bias exists. As in the case of authors, silence on the part of reviewers concerning potential conflicts may mean either that conflicts exist and the reviewer has failed to disclose them or conflicts do not exist. Reviewers must therefore also be asked to state explicitly whether conflicts do or do not exist. Reviewers must not use knowledge of the work, before its publication, to further their own interests.

Editors who make final decisions about manuscripts must have no personal, professional, or financial involvement in any of the issues they might judge. Other members of the editorial staff, if they participate in editorial decisions, must provide editors with a current description of their

financial interests (as they might relate to editorial judgments) and recuse themselves from any decisions in which a conflict of interest exists. Editorial staff must not use information gained through working with manuscripts for private gain. Editors should publish regular disclosure statements about potential conflicts of interests related to the commitments of journal staff.

II.E. Privacy and Confidentiality

II. E.1. Patients and Study Participants

Patients have a right to privacy that should not be violated without informed consent. Identifying information, including names, initials, or hospital numbers, should not be published in written descriptions, photographs, or pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that an identifiable patient be shown the manuscript to be published. Authors should disclose to these patients whether any potential identifiable material might be available via the Internet as well as in print after publication. Patient consent should be written and archived either with the journal, the authors, or both, as dictated by local regulations or laws. Applicable laws vary from locale to locale, and journals should establish their own policies with legal guidance.

Nonessential identifying details should be omitted. Informed consent should be obtained if there is any doubt that anonymity can be maintained. For example, masking the eye region in photographs of patients is inadequate protection of anonymity. If identifying characteristics are altered to protect anonymity, such as in genetic pedigrees, authors should provide assurance, and editors should so note, that such alterations do not distort scientific meaning.

The requirement for informed consent should be included in the journal's Instructions for Authors. When informed consent has been obtained, it should be indicated in the published article.

II.E.2. Authors and Reviewers

Manuscripts must be reviewed with due respect for authors' confidentiality. In submitting their manuscripts for review, authors entrust editors with the results of their scientific work and creative effort, on which their reputation and career may depend. Authors' rights may be violated by disclosure of the confidential details during review of their manuscript. Reviewers also have rights to confidentiality, which must be respected by the editor. Confidentiality may have to be breached if dishonesty or fraud is alleged but otherwise must be honored.

Editors must not disclose information about manuscripts (including their receipt, content, status in the reviewing process, criticism by reviewers, or ultimate fate) to anyone other than the authors and reviewers. This includes requests to use the materials for legal proceedings.

Editors must make clear to their reviewers that manuscripts sent for review are privileged communications and are the private property of the authors. Therefore, reviewers and members of the editorial staff must respect the authors' rights by not publicly discussing the authors' work or appropriating their ideas before the manuscript is published. Reviewers must not be allowed to make copies of the manuscript for their files and must be prohibited from sharing it with others,

except with the editor's permission. Reviewers should return or destroy copies of manuscripts after submitting reviews. Editors should not keep copies of rejected manuscripts.

Reviewer comments should not be published or otherwise publicized without permission of the reviewer, author, and editor.

Opinions differ on whether reviewers should remain anonymous. Authors should consult the Information for Authors of the journal to which they have chosen to submit a manuscript to determine whether reviews are anonymous. When comments are not signed, the reviewers' identity must not be revealed to the author or anyone else without the reviewers' permission.

Some journals publish reviewers' comments with the manuscript. No such procedure should be adopted without the consent of the authors and reviewers. However, reviewers' comments should be sent to other persons reviewing the same manuscript, which helps reviewers learn from the review process. Reviewers also may be notified of the editor's decision to accept or reject a manuscript.

II.F. Protection of Human Subjects and Animals in Research

When reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 (5). If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. When reporting experiments on animals, authors should indicate whether the institutional and national guide for the care and use of laboratory animals was followed.

III. Publishing and Editorial Issues Related to Publication in Biomedical Journals

III.A. Obligation to Publish Negative Studies

Editors should consider seriously for publication any carefully done study of an important question, relevant to their readers, whether the results for the primary or any additional outcome are statistically significant. Failure to submit or publish findings because of lack of statistical significance is an important cause of publication bias.

III.B. Corrections, Retractions and "Expressions of Concern"

Editors must assume initially that authors are reporting work based on honest observations. Nevertheless, two types of difficulty may arise.

First, errors may be noted in published articles that require the publication of a correction or erratum on part of the work. The corrections should appear on a numbered page, be listed in the Table of Contents, include the complete original citation, and link to the original article and vice versa if online. It is conceivable that an error could be so serious as to vitiate the entire body of the work, but this is unlikely and should be addressed by editors and authors on an individual basis. Such an error should not be confused with inadequacies exposed by the emergence of new

scientific information in the normal course of research. The latter requires no corrections or withdrawals.

The second type of difficulty is scientific fraud. If substantial doubts arise about the honesty or integrity of work, either submitted or published, it is the editor's responsibility to ensure that the question is appropriately pursued, usually by the authors' sponsoring institution. Ordinarily it is not the responsibility of the editor to conduct a full investigation or to make a determination; that responsibility lies with the institution where the work was done or with the funding agency. The editor should be promptly informed of the final decision, and if a fraudulent paper has been published, the journal must print a retraction. If this method of investigation does not result in a satisfactory conclusion, the editor may choose to conduct his or her own investigation. As an alternative to retraction, the editor may choose to publish an expression of concern about aspects of the conduct or integrity of the work.

The retraction or expression of concern, so labeled, should appear on a numbered page in a prominent section of the print journal as well as in the online version, be listed in the Table of Contents page, and include in its heading the title of the original article. It should not simply be a letter to the editor. Ideally, the first author of the retraction should be the same as that of the article, although under certain circumstances the editor may accept retractions by other responsible persons. The text of the retraction should explain why the article is being retracted and include a complete citation reference to that article.

The validity of previous work by the author of a fraudulent paper cannot be assumed. Editors may ask the author's institution to assure them of the validity of earlier work published in their journals or to retract it. If this is not done, editors may choose to publish an announcement expressing concern that the validity of previously published work is uncertain.

Editors who have questions related to editorial or scientific misconduct may find it useful to consult the excellent flow charts that the Committee on Publication Ethics (COPE) has developed (http://www.publicationethics.org.uk). COPE, which was formed in 1997, is a forum in which editors of peer-reviewed journals can discuss issues related to the integrity of the scientific record; it supports and encourages editors to report, catalogue, and instigate investigations into ethical problems in the publication process. COPE's major objective is to provide a sounding board for editors struggling with how best to deal with possible breaches in research and publication ethics.

III.C. Copyright

Many biomedical journals ask authors to transfer copyright to the journal. However, an increasing number of "open-access" journals do not require transfer of copyright. Editors should make their position on copyright transfer clear to authors and to others who might be interested in using editorial content from their journals. The copyright status of articles in a given journal can vary: Some content cannot be copyrighted (for example, articles written by employees of the U.S. and some other governments in the course of their work); editors may agree to waive copyright on others; and still others may be protected under serial rights (that is, use in publications other than journals, including electronic publications, is permitted).

III.D. Overlapping Publications

III.D.1. Duplicate Submission

Most biomedical journals will not consider manuscripts that are simultaneously being considered by other journals. Among the principal considerations that have led to this policy are: 1) the potential for disagreement when two (or more) journals claim the right to publish a manuscript that has been submitted simultaneously to more than one; and 2) the possibility that two or more journals will unknowingly and unnecessarily undertake the work of peer review, edit the same manuscript, and publish the same article.

However, editors of different journals may decide to simultaneously or jointly publish an article if they believe that doing so would be in the best interest of public health.

III.D.2. Redundant Publication

Redundant (or duplicate) publication is publication of a paper that overlaps substantially with one already published in print or electronic media.

Readers of primary source periodicals, whether print or electronic, deserve to be able to trust that what they are reading is original unless there is a clear statement that the author and editor are intentionally republishing an article. The bases of this position are international copyright laws, ethical conduct, and cost-effective use of resources. Duplicate publication of original research is particularly problematic, since it can result in inadvertent double counting or inappropriate weighting of the results of a single study, which distorts the available evidence.

Most journals do not wish to receive papers on work that has already been reported in large part in a published article or is contained in another paper that has been submitted or accepted for publication elsewhere, in print or in electronic media. This policy does not preclude the journal considering a paper that has been rejected by another journal, or a complete report that follows publication of a preliminary report, such as an abstract or poster displayed at a professional meeting. It also does not prevent journals from considering a paper that has been presented at a scientific meeting but was not published in full or that is being considered for publication in a proceedings or similar format. Press reports of scheduled meetings are not usually regarded as breaches of this rule, but additional data or copies of tables and illustrations should not amplify such reports. The ICMJE does not consider results posted in clinical trial registries as previous publication if the results are presented in the registry in the form of a brief structured abstract or table. The Results registry should either cite the full publication or include a statement that indicates that the report has not been published in a peer-reviewed journal.

When submitting a paper, the author must always make a complete statement to the editor about all submissions and previous reports (including meeting presentations and posting of results in registries) that might be regarded as redundant or duplicate publication. The author must alert the editor if the manuscript includes subjects about which the authors have published a previous report or have submitted a related report to another publication. Any such report must be referred to and referenced in the new paper. Copies of such material should be included with the submitted manuscript to help the editor decide how to handle the matter.

If redundant or duplicate publication is attempted or occurs without such notification, authors should expect editorial action to be taken. At the least, prompt rejection of the submitted

manuscript should be expected. If the editor was not aware of the violations and the article has already been published, then a notice of redundant or duplicate publication will probably be published with or without the author's explanation or approval.

Preliminary reporting to public media, governmental agencies, or manufacturers of scientific information described in a paper or a letter to the editor that has been accepted but not yet published violates the policies of many journals. Such reporting may be warranted when the paper or letter describes major therapeutic advances or public health hazards, such as serious adverse effects of drugs, vaccines, other biological products, or medicinal devices, or reportable diseases. This reporting should not jeopardize publication, but should be discussed with and agreed upon by the editor in advance.

III.D.3. Acceptable Secondary Publication

Certain types of articles, such as guidelines produced by governmental agencies and professional organizations, may need to reach the widest possible audience. In such instances, editors sometimes deliberately publish material that is also being published in other journals, with the agreement of the authors and the editors of those journals. Secondary publication for various other reasons, in the same or another language, especially in other countries, is justifiable and can be beneficial provided that the following conditions are met.

1. The authors have received approval from the editors of both journals; the editor concerned with secondary publication must have a photocopy, reprint, or manuscript of the primary version.

2. The priority of the primary publication is respected by a publication interval of at least 1 week (unless specifically negotiated otherwise by both editors).

3. The paper for secondary publication is intended for a different group of readers; an abbreviated version could be sufficient.

4. The secondary version faithfully reflects the data and interpretations of the primary version.

5. The footnote on the title page of the secondary version informs readers, peers, and documenting agencies that the paper has been published in whole or in part and states the primary reference. A suitable footnote might read: "This article is based on a study first reported in the [title of journal, with full reference]."

Permission for such secondary publication should be free of charge.

6. The title of the secondary publication should indicate that it is a secondary publication (complete republication, abridged republication, complete translation, or abridged translation) of a primary publication. Of note, the NLM does not consider translations to be "republications" and does not cite or index translations when the original article was published in a journal that is indexed in MEDLINE.

7. Editors of journals that simultaneously publish in multiple languages should understand that NLM indexes the primary language version. When the full text of an article appears in more than one language in a journal issue (such as Canadian journals with the article in both English and French), both languages are indicated in the MEDLINE citation (for example, Mercer K. The

relentless challenge in health care. Healthc Manage Forum. 2008 Summer;21(2):4-5. English, French. No abstract available. PMID:18795553.)

III.D.4. Competing Manuscripts Based on the Same Study

Publication of manuscripts to air the disputes of co-investigators may waste journal space and confuse readers. On the other hand, if editors knowingly publish a manuscript written by only some of a collaborating team, they could be denying the rest of the team their legitimate co-authorship rights and journal readers access to legitimate differences of opinion about the interpretation of a study.

Two kinds of competing submissions are considered: submissions by coworkers who disagree on the analysis and interpretation of their study, and submissions by coworkers who disagree on what the facts are and which data should be reported.

Setting aside the unresolved question of ownership of the data, the following general observations may help editors and others address such problems.

III. D.4.a. Differences in Analysis or Interpretation

If the dispute centers on the analysis or interpretation of data, the authors should submit a manuscript that clearly presents both versions. The difference of opinion should be explained in a cover letter. The normal process of peer and editorial review may help the authors to resolve their disagreement regarding analysis or interpretation.

If the dispute cannot be resolved and the study merits publication, both versions should be published. Options include publishing two papers on the same study, or a single paper with two analyses or interpretations. In such cases, it would be appropriate for the editor to publish a statement outlining the disagreement and the journal's involvement in attempts to resolve it.

III.D.4. b. Differences in Reported Methods or Results

If the dispute centers on differing opinions of what was actually done or observed during the study, the journal editor should refuse publication until the disagreement is resolved. Peer review cannot be expected to resolve such problems. If there are allegations of dishonesty or fraud, editors should inform the appropriate authorities; authors should be notified of an editor's intention to report a suspicion of research misconduct.

III.D.5. Competing Manuscripts Based on the Same Database

Editors sometimes receive manuscripts from separate research groups that have analyzed the same data set (for example, from a public database). The manuscripts may differ in their analytic methods, conclusions, or both. Each manuscript should be considered separately. If interpretation of the data is very similar, it is reasonable but not mandatory for editors to give preference to the manuscript that was received first. However, editorial consideration of multiple submissions may be justified under these circumstances, and there may even be a good reason to publish more than one manuscript because different analytical approaches may be complementary and equally valid.

III.E. Correspondence

The corresponding author/guarantor has primary responsibility for correspondence with the journal, but the ICMJE recommends that editors send a copy of any correspondence to all listed authors.

Biomedical journals should provide the readership with a mechanism for submitting comments, questions, or criticisms about published articles, as well as brief reports and commentary unrelated to previously published articles. This probably but not necessarily takes the form of a correspondence section or column. The authors of articles discussed in correspondence should be given an opportunity to respond, preferably in the same issue in which the original correspondence appears. Authors of correspondence should be asked to declare any competing or conflicting interests.

Published correspondence may be edited for length, grammatical correctness, and journal style. Alternatively, editors may choose to publish unedited correspondence, for example in rapid-response sections on the Internet. The journal should declare its editorial practices in this regard. Authors should approve editorial changes that alter the substance or tone of a letter or response. In all instances, editors must make an effort to screen out discourteous, inaccurate, or libelous statements and should not allow ad hominem arguments intended to discredit opinions or findings.

Although editors have the prerogative to reject correspondence that is irrelevant, uninteresting, or lacking cogency, they have a responsibility to allow a range of opinions to be expressed. The correspondence column should not be used merely to promote the journal's or the editors' point of view.

In the interests of fairness and to keep correspondence within manageable proportions, journals may want to set time limits for responding to published material and for debate on a given topic. Journals should also decide whether they would notify authors when correspondence bearing on their published work is going to appear in standard or rapid-response sections. Journals should also set policy with regard to the archiving of unedited correspondence that appears online. These policies should be published both in print and electronic versions of the journal.

III.F. Supplements, Theme Issues, and Special Series

Supplements are collections of papers that deal with related issues or topics, are published as a separate issue of the journal or as part of a regular issue, and are usually funded by sources other than the journal's publisher. Supplements can serve useful purposes: education, exchange of research information, ease of access to focused content, and improved cooperation between academic and corporate entities. Because funding sources can bias the content of supplements through the choice of topics and viewpoints, journals should consider adopting the following principles. These same principles apply to theme issues or special series that have external funding and/or guest editors.

1. The journal editor must take full responsibility for the policies, practices, and content of supplements, including complete control of the decision to publish all portions of the supplement. Editing by the funding organization should not be permitted.

2. The journal editor must retain the authority to send supplement manuscripts for external peer review and to reject manuscripts submitted for the supplement. These conditions should be made known to authors and external supplement editors before beginning editorial work on the supplement.

3. The journal editor must approve the appointment of any external editor of the supplement and take responsibility for the work of the external editor.

4. The sources of funding for the research, publication, and products of the funding source that are considered in the supplement should be clearly stated and prominently located in the supplement, preferably on each page. Whenever possible, supplements should be funded by more than one sponsor.

5. Advertising in supplements should follow the same policies as those of the rest of the journal.

6. Journal editors must enable readers to distinguish readily between ordinary editorial pages and supplement pages.

7. Journal editors and supplement editors must not accept personal favors or remuneration from sponsors of supplements.

8. Secondary publication in supplements (republication of papers published elsewhere) should be clearly identified by the citation of the original paper. Supplements should avoid redundant or duplicate publication. Supplements should not republish research results, but republication of guidelines or other material in the public interest might be appropriate.

9. The principles of authorship and disclosure of potential conflicts of interest discussed elsewhere in this document should be applied to supplements.

III.G. Electronic Publishing

Most biomedical journals are now published in electronic as well as print versions, and some are published only in electronic form. Because electronic publishing (which includes the Internet) is the same as publishing in print, in the interests of clarity and consistency the recommendations of this document should be applied to electronically published medical and health information.

The nature of electronic publication requires some special considerations, both within and beyond this document. At a minimum, Web sites should indicate the following: names, appropriate credentials, affiliations, and relevant conflicts of interest of editors, authors, and contributors; documentation and attribution of references and sources for all content; information about copyright; disclosure of site ownership; and disclosure of sponsorship, advertising, and commercial funding.

Linking from one health or medical Internet site to another may be perceived as an implicit recommendation of the quality of the second site. Journals thus should exercise caution in linking to other sites; when users are linking to another site, it may be helpful to provide an explicit statement that they are leaving the journal's site. Links to other sites posted as a result of

financial considerations should be clearly indicated as such. All dates of content posting and updating should be indicated. In electronic layout as in print, advertising and promotional messages should not be juxtaposed with editorial content, and commercial content should be clearly identified as such.

Electronic publication is in flux. Editors should develop, make available to authors, and implement policies on issues unique to electronic publishing. These issues include archiving, error correction, version control, choice of the electronic or print version of the journal as the journal of record, and publication of ancillary material.

Under no circumstances should a journal remove an article from its Web site or archive. If a correction or retraction becomes necessary, the explanation must be labeled appropriately and communicated as soon as possible on a citable page in a subsequent issue of the journal.

Preservation of electronic articles in a permanent archive is essential for the historical record. Access to the archive should be immediate and should be controlled by a third party, such as a library, instead of the publisher. Deposition in multiple archives is encouraged.

III.H. Advertising

Most medical journals carry advertising, which generates income for their publishers, but advertising must not be allowed to influence editorial decisions. Journals should have formal, explicit, written policies for advertising in both print and electronic versions; Web site advertising policy should parallel that for the print version to the extent possible. Editors must have full and final authority for approving advertisements and enforcing advertising policy.

When possible, editors should make use of the judgments of independent bodies for reviewing advertising. Readers should be able to distinguish readily between advertising and editorial material. The juxtaposition of editorial and advertising material on the same products or subjects should be avoided. Interleafing advertising pages within articles interrupts the flow of editorial content and should be discouraged. Advertising should not be sold on the condition that it will appear in the same issue as a particular article.

Journals should not be dominated by advertising, but editors should be careful about publishing advertisements from only one or two advertisers, as readers may perceive that these advertisers have influenced the editor.

Journals should not carry advertisements for products that have proved to be seriously harmful to health—for example, tobacco. Editors should ensure that existing regulatory or industry standards for advertisements specific to their country are enforced, or develop their own standards. The interests of organizations or agencies should not control classified and other nondisplay advertising, except where required by law. Finally, editors should consider all criticisms of advertisements for publication.

III. I. Medical Journals and the General Media

The public’s interest in news of medical research has led the popular media to compete vigorously for information about research. Researchers and institutions sometimes encourage

reporting research in the nonmedical media before full publication in a scientific journal by holding a press conference or giving interviews.

The public is entitled to important medical information within a reasonable amount of time, and editors have a responsibility to facilitate the process. Biomedical journals are published primarily for their readers, but the general public has a legitimate interest in their content: An appropriate balance between these considerations should guide the journal's interaction with the media. Doctors in practice need to have reports available in full detail before they can advise their patients about the reports' conclusions. Moreover, media reports of scientific research before the work has been peer reviewed and fully vetted may lead to dissemination of inaccurate or premature conclusions.

An embargo system has been established in some countries to prevent publication of stories in the general media before publication of the original research in the journal. The embargo creates a "level playing field," which most reporters appreciate since it minimizes the pressure on them to publish stories which they have not had time to prepare carefully. Consistency in the timing of public release of biomedical information is also important in minimizing economic chaos, since some articles contain information that has great potential to influence financial markets. On the other hand, the embargo system has been challenged as being self-serving of journals' interests and an impediment to rapid dissemination of scientific information.

Editors may find the following recommendations useful as they seek to establish policies on these issues.

- Editors can foster the orderly transmission of medical information from researchers, through peer-reviewed journals, to the public. This can be accomplished by an agreement with authors that they will not publicize their work while their manuscript is under consideration or awaiting publication and an agreement with the media that they will not release stories before publication of the original research in the journal, in return for which the journal will cooperate with them in preparing accurate stories.

- Editors need to keep in mind that an embargo system works on the honor system; no formal enforcement or policing mechanism exists. The decision of a significant number of media outlets or biomedical journals not to respect the embargo system would lead to its rapid dissolution.

- Very little medical research has such clear and urgently important clinical implications for the public's health that the news must be released before full publication in a journal. However, if such exceptional circumstances occur, the appropriate authorities responsible for public health should decide whether to disseminate information to physicians and the media in advance and should be responsible for this decision. If the author and the appropriate authorities wish to have a manuscript considered by a particular journal, the editor should be consulted before any public release. If editors acknowledge the need for immediate release, they should waive their policies limiting prepublication publicity.

- Policies designed to limit prepublication publicity should not apply to accounts in the media of presentations at scientific meetings or to the abstracts from these meetings (see Redundant Publication). Researchers who present their work at a scientific meeting

should feel free to discuss their presentations with reporters, but they should be discouraged from offering more detail about their study than was presented in the talk.

- When an article is soon to be published, editors should help the media prepare accurate reports by providing news releases, answering questions, supplying advance copies of the journal, or referring reporters to the appropriate experts. This assistance should be contingent on the media's cooperation in timing the release of a story to coincide with publication of the article.
- Editors, authors, and the media should apply the above-stated principles to material released early in electronic versions of journals.

III.J. Obligation to Register Clinical Trials

The ICMJE believes that it is important to foster a comprehensive, publicly available database of clinical trials. The ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like.

The ICMJE member journals will require, as a condition of consideration for publication in their journals, registration in a public trials registry. The details of this policy are contained in a series of editorials (see editorials, under Frequently Asked Questions). The ICMJE encourages editors of other biomedical journals to adopt similar policy.

The ICMJE does not advocate one particular registry, but its member journals will require authors to register their trial in a registry that meets several criteria. The registry must be accessible to the public at no charge. It must be open to all prospective registrants and managed by a not-for-profit organization. There must be a mechanism to ensure the validity of the registration data, and the registry should be electronically searchable. An acceptable registry must include at minimum the data elements listed in Table 1. Trial registration with missing fields or fields that contain uninformative terminology is inadequate.

It is important to note that the ICMJE requires registration of trial methodology but does not require registration of trial results; it recognizes the potential problems that could arise from the posting of research results that have not been subjected to an independent peer-review process. However, the ICMJE understands that the U.S. Food and Drug Administration Amendments Act of 2007 (FDAAA) does require researchers to register results. The ICMJE will not consider to be previous publication results posted in the same primary clinical trial registry as the initial registration if the results are posted in the tabular form dictated by the FDAAA. Researchers should be aware that editors of journals that follow the ICMJE recommendations may consider more detailed description of trial results and results published in registries other than the primary registry (in the case of FDAAA, ClinicalTrials.gov) to be prior publication. The ICMJE anticipates that the climate for results registration will change dramatically over coming years and the ICMJE may need to amend these recommendations as additional agencies institute other mandates related to results registration.

The ICMJE recommends that journals publish the trial registration number at the end of the abstract. The ICMJE also recommends that, whenever a registration number is available, authors list the registration number the first time they use a trial acronym to refer to either the trial they are reporting or to other trials that they mention in the manuscript.

IV. Manuscript Preparation and Submission

IV.A. Preparing a Manuscript for Submission to a Biomedical Journal

Editors and reviewers spend many hours reading manuscripts, and therefore appreciate receiving manuscripts that are easy to read and edit. Much of the information in a journal's Instructions to Authors is designed to accomplish that goal in ways that meet each journal's particular editorial needs. The following information provides guidance in preparing manuscripts for any journal.

IV.A.1.a. General Principles

The text of observational and experimental articles is usually (but not necessarily) divided into the following sections: Introduction, Methods, Results, and Discussion. This so-called "IMRAD" structure is not an arbitrary publication format but rather a direct reflection of the process of scientific discovery. Long articles may need subheadings within some sections (especially Results and Discussion) to clarify their content. Other types of articles, such as case reports, reviews, and editorials, probably need to be formatted differently.

Electronic formats have created opportunities for adding details or whole sections, layering information, cross-linking or extracting portions of articles, and the like only in the electronic version. Authors need to work closely with editors in developing or using such new publication formats and should submit supplementary electronic material for peer review.

Double spacing all portions of the manuscript— including the title page, abstract, text, acknowledgments, references, individual tables, and legends—and generous margins make it possible for editors and reviewers to edit the text line by line and add comments and queries directly on the paper copy. If manuscripts are submitted electronically, the files should be double-spaced to facilitate printing for reviewing and editing.

Authors should number all of the pages of the manuscript consecutively, beginning with the title page, to facilitate the editorial process.

IV.A.1.b. Reporting Guidelines for Specific Study Designs

Research reports frequently omit important information. Reporting guidelines (Table 2) have been developed for a number of study designs that some journals may ask authors to follow. Authors should consult the Information for Authors of the journal they have chosen.

The general requirements listed in the next section relate to reporting essential elements for all study designs. Authors are encouraged also to consult reporting guidelines relevant to their specific research design. For reports of randomized, controlled trials, authors should refer to the CONSORT statement. This guideline provides a set of recommendations comprising a list of items to report and a patient flow diagram.

IV.A.2. Title Page

The title page should carry the following information:

1. Article title. Concise titles are easier to read than long, convoluted ones. Titles that are too short may, however, lack important information, such as study design (which is particularly important in identifying randomized, controlled trials). Authors should include all information in the title that will make electronic retrieval of the article both sensitive and specific.

2. Authors' names and institutional affiliations. Some journals publish each author's highest academic degree(s), while others do not.

3. The name of the department(s) and institution(s) to which the work should be attributed.

4. Disclaimers, if any.

5. Contact information for corresponding authors. The name, mailing address, telephone and fax numbers, and e-mail address of the author responsible for correspondence about the manuscript (the "corresponding author;" this author may or may not be the "guarantor" for the integrity of the study). The corresponding author should indicate clearly whether his or her e-mail address can be published.

6. The name and address of the author to whom requests for reprints should be addressed or a statement that reprints are not available from the authors.

7. Source(s) of support in the form of grants, equipment, drugs, or all of these.

8. A running head. Some journals request a short running head or footline, usually no more than 40 characters (including letters and spaces) at the foot of the title page. Running heads are published in most journals, but are also sometimes used within the editorial office for filing and locating manuscripts.

9. Word counts. A word count for the text only (excluding abstract, acknowledgments, figure legends, and references) allows editors and reviewers to assess whether the information contained in the paper warrants the amount of space devoted to it, and whether the submitted manuscript fits within the journal's word limits. A separate word count for the Abstract is useful for the same reason.

10. The number of figures and tables. It is difficult for editorial staff and reviewers to determine whether the figures and tables that should have accompanied a manuscript were actually included unless the numbers of figures and tables are noted on the title page.

IV.A.3. Conflict of Interest Notification Page

To prevent the information on potential conflicts of interest from being overlooked or misplaced, it needs to be part of the manuscript. However, it should also be included on a separate page or pages immediately following the title page. Individual journals may differ in where they include

this information, and some journals do not send information on conflicts of interest to reviewers. (***See Section II. D. Conflicts of Interest***.)

IV.A.4. Abstract

The abstract (requirements for length and format vary) should follow the title page. It should provide the context or background for the study and should state the study's purpose, basic procedures (selection of study subjects or laboratory animals, observational and analytical methods), main findings (giving specific effect sizes and their statistical significance, if possible), and principal conclusions. It should emphasize new and important aspects of the study or observations. Articles on clinical trials should contain abstracts that include the items that the CONSORT group has identified as essential (http://www.consort-statement.org/?=1190).

Because abstracts are the only substantive portion of the article indexed in many electronic databases, and the only portion many readers read, authors need to be careful that they accurately reflect the content of the article. Unfortunately, the information contained in many abstracts differs from that in the text (6). The format required for structured abstracts differs from journal to journal, and some journals use more than one format; authors need to prepare their abstracts in the format specified by the journal they have chosen.

The ICMJE recommends that journals publish the trial registration number at the end of the abstract. The ICMJE also recommends that, whenever a registration number is available, authors list that number the first time they use a trial acronym to refer to either the trial they are reporting or to other trials that they mention in the manuscript.

IV.A.5. Introduction

Provide a context or background for the study (that is, the nature of the problem and its significance). State the specific purpose or research objective of, or hypothesis tested by, the study or observation; the research objective is often more sharply focused when stated as a question. Both the main and secondary objectives should be clear, and any prespecified subgroup analyses should be described. Provide only directly pertinent references, and do not include data or conclusions from the work being reported.

IV.A.6. Methods

The Methods section should include only information that was available at the time the plan or protocol for the study was being written; all information obtained during the study belongs in the Results section.

IV.A.6.a. Selection and Description of Participants

Describe your selection of the observational or experimental participants (patients or laboratory animals, including controls) clearly, including eligibility and exclusion criteria and a description of the source population. Because the relevance of such variables as age and sex to the object of research is not always clear, authors should explain their use when they are included in a study report--for example, authors should explain why only participants of certain ages were included or why women were excluded. The guiding principle should be clarity about how and why a

study was done in a particular way. When authors use such variables as race or ethnicity, they should define how they measured these variables and justify their relevance.

IV.A.6.b. Technical information

Identify the methods, apparatus (give the manufacturer's name and address in parentheses), and procedures in sufficient detail to allow others to reproduce the results. Give references to established methods, including statistical methods (see below); provide references and brief descriptions for methods that have been published but are not well-known; describe new or substantially modified methods, give the reasons for using them, and evaluate their limitations. Identify precisely all drugs and chemicals used, including generic name(s), dose(s), and route(s) of administration.

Authors submitting review manuscripts should include a section describing the methods used for locating, selecting, extracting, and synthesizing data. These methods should also be summarized in the abstract.

IV.A.6.c. Statistics

Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results. When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Avoid relying solely on statistical hypothesis testing, such as P values, which fail to convey important information about effect size. References for the design of the study and statistical methods should be to standard works when possible (with pages stated). Define statistical terms, abbreviations, and most symbols. Specify the computer software used.

IV.A.7. Results

Present your results in logical sequence in the text, tables, and illustrations, giving the main or most important findings first. Do not repeat all the data in the tables or illustrations in the text; emphasize or summarize only the most important observations. Extra or supplementary materials and technical detail can be placed in an appendix where they will be accessible but will not interrupt the flow of the text, or they can be published solely in the electronic version of the journal.

When data are summarized in the Results section, give numeric results not only as derivatives (for example, percentages) but also as the absolute numbers from which the derivatives were calculated, and specify the statistical methods used to analyze them. Restrict tables and figures to those needed to explain the argument of the paper and to assess supporting data. Use graphs as an alternative to tables with many entries; do not duplicate data in graphs and tables. Avoid nontechnical uses of technical terms in statistics, such as "random" (which implies a randomizing device), "normal," "significant," "correlations," and "sample."

Where scientifically appropriate, analyses of the data by such variables as age and sex should be included.

IV.A.8. Discussion

Emphasize the new and important aspects of the study and the conclusions that follow from them. Do not repeat in detail data or other information given in the Introduction or the Results section. For experimental studies, it is useful to begin the discussion by summarizing briefly the main findings, then explore possible mechanisms or explanations for these findings, compare and contrast the results with other relevant studies, state the limitations of the study, and explore the implications of the findings for future research and for clinical practice.

Link the conclusions with the goals of the study but avoid unqualified statements and conclusions not adequately supported by the data. In particular, avoid making statements on economic benefits and costs unless the manuscript includes the appropriate economic data and analyses. Avoid claiming priority or alluding to work that has not been completed. State new hypotheses when warranted, but label them clearly as such.

IV.A.9. References

IV.A.9.a. General Considerations Related to References

Although references to review articles can be an efficient way to guide readers to a body of literature, review articles do not always reflect original work accurately. Readers should therefore be provided with direct references to original research sources whenever possible. On the other hand, extensive lists of references to original work on a topic can use excessive space on the printed page. Small numbers of references to key original papers often serve as well as more exhaustive lists, particularly since references can now be added to the electronic version of published papers, and since electronic literature searching allows readers to retrieve published literature efficiently.

Avoid using abstracts as references. References to papers accepted but not yet published should be designated as “in press” or “forthcoming”; authors should obtain written permission to cite such papers as well as verification that they have been accepted for publication. Information from manuscripts submitted but not accepted should be cited in the text as “unpublished observations” with written permission from the source.

Avoid citing a “personal communication” unless it provides essential information not available from a public source, in which case the name of the person and date of communication should be cited in parentheses in the text. For scientific articles, obtain written permission and confirmation of accuracy from the source of a personal communication.

Some but not all journals check the accuracy of all reference citations; thus, citation errors sometimes appear in the published version of articles. To minimize such errors, verify references against the original documents. Authors are responsible for checking that none of the references cite retracted articles except in the context of referring to the retraction. For articles published in journals indexed in MEDLINE, the ICMJE considers PubMed the authoritative source for information about retractions. Authors can identify retracted articles in MEDLINE by using the following search term, where pt in square brackets stands for publication type: Retracted publication [pt] in PubMed.

IV.A.9.b. Reference Style and Format

The Uniform Requirements style for references is based largely on an American National Standards Institute style adapted by the NLM for its databases. Authors should consult NLM's Citing Medicine for information on its recommended formats for a variety of reference types.

References should be numbered consecutively in the order in which they are first mentioned in the text. Identify references in text, tables, and legends by Arabic numerals in parentheses. References cited only in tables or figure legends should be numbered in accordance with the sequence established by the first identification in the text of the particular table or figure. The titles of journals should be abbreviated according to the style used in the list of Journals Indexed for MEDLINE, posted by the NLM on the Library's web site. Journals vary on whether they ask authors to cite electronic references within parentheses in the text or in numbered references following the text. Authors should consult with the journal to which they plan to submit their work.

IV.A.10. Tables

Tables capture information concisely and display it efficiently; they also provide information at any desired level of detail and precision. Including data in tables rather than text frequently makes it possible to reduce the length of the text.

Type or print each table with double spacing on a separate sheet of paper. Number tables consecutively in the order of their first citation in the text and supply a brief title for each. Do not use internal horizontal or vertical lines. Give each column a short or an abbreviated heading. Authors should place explanatory matter in footnotes, not in the heading. Explain all nonstandard abbreviations in footnotes, and use the following symbols, in sequence:

*,†,‡,§,||,¶,**,††,‡‡

Identify statistical measures of variations, such as standard deviation and standard error of the mean.

Be sure that each table is cited in the text.

If you use data from another published or unpublished source, obtain permission and acknowledge that source fully.

Additional tables containing backup data too extensive to publish in print may be appropriate for publication in the electronic version of the journal, deposited with an archival service, or made available to readers directly by the authors. An appropriate statement should be added to the text to inform readers that this additional information is available and where it is located. Submit such tables for consideration with the paper so that they will be available to the peer reviewers.

IV.A.11. Illustrations (Figures)

Figures should be either professionally drawn and photographed, or submitted as photographic-quality digital prints. In addition to requiring a version of the figures suitable for printing, some journals now ask authors for electronic files of figures in a format (for example, JPEG or GIF) that will produce high-quality images in the Web version of the journal; authors should review

the images of such files on a computer screen before submitting them to be sure they meet their own quality standards.

For x-ray films, scans, and other diagnostic images, as well as pictures of pathology specimens or photomicrographs, send sharp, glossy, black-and-white or color photographic prints, usually 127 x 173 mm (5 x 7 inches). Although some journals redraw figures, many do not. Letters, numbers, and symbols on figures should therefore be clear and consistent throughout, and large enough to remain legible when the figure is reduced for publication. Figures should be made as self-explanatory as possible, since many will be used directly in slide presentations. Titles and detailed explanations belong in the legends--not on the illustrations themselves.

Photomicrographs should have internal scale markers. Symbols, arrows, or letters used in photomicrographs should contrast with the background.

Photographs of potentially identifiable people must be accompanied by written permission to use the photograph.

Figures should be numbered consecutively according to the order in which they have been cited in the text. If a figure has been published previously, acknowledge the original source and submit written permission from the copyright holder to reproduce the figure. Permission is required irrespective of authorship or publisher except for documents in the public domain.

For illustrations in color, ascertain whether the journal requires color negatives, positive transparencies, or color prints. Accompanying drawings marked to indicate the region to be reproduced might be useful to the editor. Some journals publish illustrations in color only if the author pays the additional cost.

Authors should consult the journal about requirements for figures submitted in electronic formats.

IV.A.12. Legends for Illustrations (Figures)

Type or print out legends for illustrations using double spacing, starting on a separate page, with Arabic numerals corresponding to the illustrations. When symbols, arrows, numbers, or letters are used to identify parts of the illustrations, identify and explain each one clearly in the legend. Explain the internal scale and identify the method of staining in photomicrographs.

IV.A.13. Units of Measurement

Measurements of length, height, weight, and volume should be reported in metric units (meter, kilogram, or liter) or their decimal multiples.

Temperatures should be in degrees Celsius. Blood pressures should be in millimeters of mercury, unless other units are specifically required by the journal.

Journals vary in the units they use for reporting hematologic, clinical chemistry, and other measurements. Authors must consult the Information for Authors of the particular journal and should report laboratory information in both local and International System of Units (SI). Editors may request that authors add alternative or non-SI units, since SI units are not universally used.

Drug concentrations may be reported in either SI or mass units, but the alternative should be provided in parentheses where appropriate.

IV.A.14. Abbreviations and Symbols

Use only standard abbreviations; use of nonstandard abbreviations can be confusing to readers. Avoid abbreviations in the title of the manuscript. The spelled-out abbreviation followed by the abbreviation in parenthesis should be used on first mention unless the abbreviation is a standard unit of measurement.

IV.B Sending the Manuscript to the Journal

An increasing number of journals now accept electronic submission of manuscripts, whether on disk, as an e-mail attachment, or by downloading directly onto the journal's Web site. Electronic submission saves time and money and allows the manuscript to be handled in electronic form throughout the editorial process (for example, when it is sent out for review). For specific instructions on electronic submission, authors should consult the journal's Instructions for Authors.

If a paper version of the manuscript is submitted, send the required number of copies of the manuscript and figures; they are all needed for peer review and editing, and the editorial office staff cannot be expected to make the required copies.

Manuscripts must be accompanied by a cover letter, which should include the following information.

- A full statement to the editor about all submissions and previous reports that might be regarded as redundant publication of the same or very similar work. Any such work should be referred to specifically and referenced in the new paper. Copies of such material should be included with the submitted paper to help the editor address the situation.

- A statement of financial or other relationships that might lead to a conflict of interest, if that information is not included in the manuscript itself or in an authors' form.

- A statement that the manuscript has been read and approved by all the authors, that the requirements for authorship as stated earlier in this document have been met, and that each author believes that the manuscript represents honest work if that information is not provided in another form (see below).

- The name, address, and telephone number of the corresponding author, who is responsible for communicating with the other authors about revisions and final approval of the proofs, if that information is not included in the manuscript itself.

The letter should give any additional information that may be helpful to the editor, such as the type or format of article in the particular journal that the manuscript represents. If the manuscript has been submitted previously to another journal, it is helpful to include the previous editor's and reviewers' comments with the submitted manuscript, along with the authors' responses to those

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V. References

A. References Cited in this Document

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B. Other Sources of Information Related to Biomedical Journals

World Association of Medical Editors (WAME)

Council of Science Editors (CSE)

European Association of Science Editors (EASE)

Cochrane Collaboration

Committee on Publication Ethics

VI. About The International Committee of Medical Journal Editors

The ICMJE is a group of general medical journal editors whose participants meet annually and fund their work on the Uniform Requirements for Manuscripts. The ICMJE invites comments on this document and suggestions for agenda items.

VII. Authors of The Uniform Requirements for Manuscripts Submitted to Biomedical Journals

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