

26. FHN Study Publication Policy

26.1 Introduction

The policy of the Study concerning publications and presentations is designed to achieve five objectives:

1. To assure timely publication of the results of the Study to the appropriate professional audiences,
2. To avoid premature publication of results that might compromise the performance of the study (such as by publication of trends of results before such trends become statistically convincing) or that might compromise the ability to publish the results in high quality peer reviewed journals (as by premature release to the lay press),
3. To maintain high standards of quality of all material published by the Study,
4. To guard against duplicate publication of results by assuring absence of overlap of materials prepared by various writing committees, and
5. To assure equitable attribution of credit to all of the professionals participating in the Study.

To accomplish these ends, it is the policy of the Study that preparation of all publications or presentations, other than materials prepared for local publicity purposes, must be assigned by the Study Chairman after consultation with Chairman of the Publications and Ancillary Studies (PAS) Committee to specifically appoint writing committees, and that all such materials must be reviewed and approved by the PAS Committee and/or the Steering Committee before publication.

26.2 Scope of policy, and exception for local publicity materials

All material to be presented orally or submitted for publication or dissemination by individuals associated with the Study and dealing with any aspect of the Study must receive prior review and approval by the PAS Committee/Steering Committee with the following exception:

Material prepared for publicity purposes either nationally or within the recruitment region of a FHN Clinical Center, or presented orally or as handouts or posters to professional audiences solely for the purposes of informing the profession of the Study and its objectives, need not be reviewed by the PAS Committee. Such material must be limited to a background discussion of hemodialysis as a treatment for end-stage renal disease and a description of the Study organization, objectives, and entrance criteria, and to results of the study that have previously been presented to a scientific body or published in a scientific journal. It must not include discussion of any previously unrepresented and unpublished Study outcomes or other citable professional reference.

26.3 Source of suggestions for publications of the study

Suggestions for topics appropriate for preparation of abstracts, peer reviewed papers, or chapters and reviews are made by the PAS Committee. In addition, all participants in the Study are invited to suggest topics appropriate for preparation as abstracts, peer reviewed papers, or chapters and reviews from the Study. Such suggestions should be made to the DCC and the Chair of the PAS Committee, who shall review the request to be certain that there is no overlap with materials previously assigned to other writing committees. Where such overlap exists, the Chair of the PAS Committee may make recommendations to the Study Chair that the suggestion be referred to an existing writing committee, that additional study participants be added to existing writing committees, or make other suggestions

to resolve the overlap. However, final decision in this matter will be made by the Study Chair after consultation with the Chair of the PAS Committee.

It is the policy of the Study to encourage non-physician professionals to prepare scientific presentations to their own professional meetings and to prepare scientific papers for their own professional journals in addition to participating in the preparation of papers for medical journals. Since the subject matter of these reports and papers may well overlap with material being prepared by writing committees for medical journals, it is the policy of the Study that under these circumstances, rather than forming a new writing committee, such non-physician professionals should be added to the existing writing committee concerned with related matters, specifically for the purposes of preparing such reports. The authors of these presentations and reports will be the members of the writing committee, with first author being the individual added to the committee for this purpose, using the appropriate authorship style described in section 4.6.

In addition, the PAS Committee will formulate and maintain a list of suggested topics that should be prepared for publication, to assure that all completed aspects of the work of the Study are reported to the scientific community in a timely fashion.

26.4 Assignment of writing committees

Topics suggested for presentation or publication that do not overlap with an existing committee will be circulated to the Principal Investigators of all clinical centers, DCC, and the NIH. These groups are requested to suggest and justify names for lead authors (Chair of writing committees) and co-authors. These names will be collated and reviewed by the PAS Committee. A recommendation for a writing committee will then be made to the Chair of the PAS Committee who will decide on the final composition of the writing committee. If a topic is suggested by a participant of the Study, the writing committee will be formed as just described except that the person making the suggestion will be considered as the potential lead author. The Principal Investigator of an ancillary study should be considered for lead author of material derived from this study. If only a subset of clinical centers participate in an ancillary study, only investigators from these centers should be considered to be on writing committees relating to this study. Appointments of writing committee chairmanships will be made in an equitable fashion to all professionals -- physicians, study coordinators, nurses, statisticians, and others -- in a fashion that recognizes the special contributions of each member of the Study to its performance. Any dispute about lead author or co-author will be settled by the Chair of the PAS Committee. In all cases, writing committees dealing with an issue that requires analysis of data by the Data Coordinating Center will have a member of the DCC assigned to it.

From time to time it may be expedient for the chairmanship of a writing committee to be reassigned to another member of that committee, or for members to be dropped from or added to a writing committee. The Chair of the PAS Committee is authorized to make such changes with the consensus of the members of the writing committee, or on his own authority where there is clear cause.

26.5 Classes of reports of the study

There are four classes of reports of the Study:

- A. Reports of the major outcomes of the Study. It is assumed that there will generally be only one or two such reports derived from each Phase of the Study.
- B. Reports addressing in detail one aspect of the Study, but in which the data are derived from the entire study.

- C. Reports of data derived from a subset of centers by members of the Study (e.g., substudies or ancillary studies), or originally conceived analyses of data from the entire Study (original analyses).
- D. Reports of investigations initiated outside the Study, but using data or samples collected by the Study. The investigators may be FHN or other investigators, but the source of the ideas and the funding for the study will have been derived outside the Study itself. Writing committees for this type are formed and presentations and publications made in accordance with the general policy rules for FHN publications. However, the Principal Investigator of an ancillary study should take primary responsibility in publishing the results of the study.

26.6 Authorship policy

The authorship policy of the Study must achieve two somewhat conflicting goals. First, it is recognized that the findings of the study, especially the findings reported in Type A and B reports, are derived from the efforts of the entire FHN professional staff. Thus, all reports, of whatever Type, must give recognition to all the participants of the Study, and reports of Types A and B must give primary recognition to the entire study professional staff. On the other hand, it is recognized that the preparation of a manuscript places special demands on the assigned writing committee, and especially on the Chair of the writing committee. Further, recognition of special effort and achievement is important in the professional careers of the study staff, and specific listing as an author is a significant motivating factor that will help assure prompt completion of writing assignments and timely publication of the results of the Study. The FHN authorship policy attempts to recognize each of these goals. The authors of FHN publications will be listed as detailed below for each type of publication.

Type A publications:

abstracts: the Frequent Hemodialysis Network (FHN) Study Group¹, presented by XXXX.

papers: the Frequent Hemodialysis Network (FHN) Study Group¹, prepared by XXXX.

¹The FHN participant box, detailed below, must be included in these papers. If a journal's publication policy does not allow authorship by a group, the authors will be listed first as in Type B publications.

Type B publications:

abstracts and papers: Authors' names, and the Frequent Hemodialysis Network (FHN) Study Group¹

¹The FHN participant box will be included in all papers if this can be arranged with the publisher. Otherwise it will be referenced in one of the Type A papers. It will not be practical to publish the entire list of participants in abstracts.

Type C and Type D publications:

abstracts and papers: authors' names and the FHN Study

¹The participant box will be included in all Type C papers if this can be arranged with the publisher. Otherwise it will be referenced in one of the Type A papers. In Type D papers, the list of participants will be referenced in all cases. It will not be practical to publish the entire list of participants in abstracts.

26.7 Listing of professional participants in the participant box

The FHN participant box will list all professionals who have participated in the Study for a minimum of one year. The participants for each participating center will be listed together, with the center Principal Investigator listed first, and identified as "P.I." followed by the other center staff listed alphabetically. Each participant will be listed only by his/her professional and academic degrees, not

by the specific position that he/she held in the study. The centers will be listed in the following order:

NIH
Study Chair
Clinical Centers (in alphabetical order)
DCC

Prior to the publication of any papers from the Study, each center will be asked to confirm and approve the listing of the personnel from that center in the Participant Box.

26.8 Acknowledgement of support and reprint addresses

Acknowledgement of grant support to be used in all papers reporting results of the Study. (In the case of ancillary studies, additional sources of support should be cited as appropriate).

The Study is supported by the Division of Kidney, Urologic and Hematologic Diseases of the National Institute of Diabetes and Digestive, and Kidney Diseases, NIH. Additional support is provided by the (list of any industrial or other support).

The following information regarding reprint requests should be included in all papers prepared for the Study. The DCC will maintain an inventory of all Study publications and will mail out the reprints.

Requests for reprints should be addressed to:

FHN Data Coordinating Center
Department of Quantitative Health Sciences, Wb4
Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195

26.9 Schedule for completion of writing assignments and resolution of overlaps between writing committees

At the time that a writing committee is constituted, the PAS Committee will establish a timetable for the completion of the writing assignment that takes into account deadlines for the publication, the amount of time that will be required for data analysis, the other commitments of the DCC, and the priority of the publication. The Chair of the Writing Committee should provide the Chair of the PAS Committee a general outline of the proposed publication within a month of receiving its assignment, to permit the PAS Committee to identify any overlap with the assignments of other writing committees, and to permit establishment of an appropriate timetable. Where overlaps of materials to be covered by different writing committees are detected, the Chair of the PAS Committee will attempt to resolve these informally with the chairs of the involved writing committees. In the event that this effort at mediation fails, the issue will be resolved by the Chair of the PAS Committee. The Chair of the PAS Committee will report at each meeting of the Steering Committee on the progress of the various writing committees.

26.10 Review of abstracts and presentations by the PAS committee

To expedite review of abstracts, oral presentations, and any other material for which there is an explicit deadline for submission, the following procedure will be used:

1. The writing committee wanting to submit an abstract, give a talk, or submit other material for which there is an explicit submission deadline shall contact the Chair of the PAS

- Committee. In the event that the Chair is unavailable, the Vice Chair may be contacted. The Chair (or Vice Chair) will name a subcommittee of two members of the PAS Committee to review the submitted material and will inform the submitter and this subcommittee of their appointment. The submitted material should be sent by the submitter directly to these two reviewers so as to reach them no fewer than seven (7) days prior to the deadline for submission.
2. The members of the subcommittee shall review the material and notify the Chair solely of their approval or disapproval. If there is unanimous approval, the PAS Committee Chair (or Vice Chair) shall inform (through the DCC) the submitter that he/she has Study approval for the submission.
 3. All materials submitted for approval in this fashion will be distributed, together with notice of the disposition, to all members of the PAS Committee and to the Chair of the Steering Committee. All approved materials will also be forwarded to the NIH Project Officer, and for record purposes to the Principal Investigator of the Data Coordinating Center, and will be distributed to the entire membership of the Steering Committee at the next meeting of that Committee.

Approval for submission of an abstract or oral presentation does not automatically grant approval of the material ultimately to be presented. This material must also be submitted for review and approval in accordance with the above rules at least seven (7) days prior to the scheduled oral or poster presentation. Normally this review will be done by the same subcommittee of the PAS Committee that reviewed the initial abstract.

1. In the case of an oral presentation, an outline of the talk and a copy of any slides to be used must be submitted for review.
2. In case of a poster presentation, the content of the poster material must be submitted for review.

26.11 Review of papers by the PAS committee

All materials for which there is no explicit deadline, and all full papers that may result in a citable scientific reference, whether or not there is a deadline for submission, must be submitted to the Chair of the PAS Committee for formal review by the entire Committee. If there is a deadline for submission of a formal paper, it is the responsibility of the submitter to be certain that it is submitted to the Chair, PAS Committee, at least 30 days prior to the deadline, to permit such review. This review will be conducted as follows:

1. The Chair, PAS Committee, shall appoint a panel of two primary reviewers, one of which must be a PAS Committee member, and one of whom may be any professional member of the Study Group with appropriate expertise. The Chair (through the DCC) shall distribute the material to all members of the PAS Committee and to the Principal Investigator of each center participating in the Study. The two members of the review panel shall each prepare and send to the Chair a written critique of the submitted material for distribution to the entire PAS Committee. The P.I.s of the various clinical centers will be given a deadline by which any comments or critiques that study personnel at their center may wish to make must be received by the Chair, PAS Committee. This mechanism will assure that each professional participating in the Study will have an opportunity to review any materials that will be submitted for publication bearing his/ her name as a participant and co-author.

2. The Chair, PAS Committee shall schedule a meeting of the Committee (generally by conference call), including review of papers and other non-time critical materials as Agenda items. The reviews of the panel members and any comments received from the center P.I.s will be distributed to the committee with the agenda.
3. While discussion of the submitted papers and other materials will be led by the two appointed reviewers, all members of the Committee will be invited to participate and all shall vote on final disposition.
4. In keeping with medical editorial traditions, there are three possible dispositions: approval of the material as submitted (possibly with some recommendations for revision that do not require re-review), non-acceptance of the material as submitted but with recommendations to the authors for revisions and resubmission, and disapproval of the material.
5. The Chair of the PAS Committee shall be responsible for communicating the decision of the Committee to the authors, together with a summary of suggestions for revision, if any. If the Committee has recommended non-acceptance of the material as submitted but with suggestions for revision and resubmission, he and the writing committee may agree not to proceed with a report to the Executive or Steering Committees at that time, pending revision and resubmission.
6. If there is a recommendation for approval or final approval or final disapproval of submitted material, or if there is a recommendation for revision which is contested by the author(s), the Chair, PAS Committee shall report this outcome in writing to the Executive Committee for final action. In the case of a dispute between the PAS Committee and the author(s), the Chair, PAS Committee shall provide a copy of the submitted material and a summary critique to the Executive Committee, and the chair of the writing committee shall be given an opportunity to submit a rebuttal.
7. The authority to grant final approval for a formal scientific paper of the Study rests with the Steering Committee, or the Executive Committee in the interim between meetings of the Steering Committee.
8. All materials submitted for approval in this fashion will be forwarded, together with notice of disposition, to the Chair of the Steering Committee. All materials receiving final approval by the Executive or Steering Committee will also be forwarded to the NIH Project Coordinator, and for record purposes to the Principal Investigator of the DCC.
9. In the event that editors of a scientific journal to which an approved FHN scientific manuscript is submitted suggest or require revisions of the manuscript, the revised manuscript must be reviewed again by the PAS Committee prior to resubmission in the same manner as described above. Generally, the Chair will appoint the same reviewers who first read the paper to review the revision, and every effort will be made to expedite such repeat reviews.

26.12 Criteria for review of materials by the PAS committee

All materials submitted to the PAS Committee will be reviewed for acceptability on two grounds:

1. Materials shall be evaluated for scientific accuracy, quality, importance, and style. The intent is to assure that all approved FHN materials reflect well on the Study.
2. Materials shall be reviewed to assure appropriateness of the content. The material shall be reviewed to assure that it conforms to the assignment to the writing committee, addressing satisfactorily the assigned topics and not encroaching on material assigned to other writing groups. In addition, the material shall be reviewed to assure that it does not divulge prematurely the outcomes or findings of the Study or compromise the eventual publication

of FHN findings in high quality peer reviewed journals. In this later regard, it must be remembered that publication of reports of more than 400 words are generally taken to constitute prior publication of a body of material and will generally preclude subsequent publication of the material in a peer reviewed journal.

26.13 Maintenance of records of publications and presentations

The DCC will maintain a record of all official publications and presentations of the FHN Study, separated into the following categories:

1. Peer reviewed papers accepted and published in professional journals
2. Invited editorials, reviews, chapters, and books
3. Abstracts published in citable journals
4. Other presentations at regional or national meetings that do not result in a citable abstract

This listing will be updated at least every six months and will be distributed to the P.I. of each center participating in the Study, together with reprints or copies of any papers, chapters, or abstracts accepted for publication since the last update. This is intended to facilitate the updating of curricula vitae and the timely submission of reports to CRCs and other such organizations within the participating centers.

26.14 Acknowledgement and acceptance of FHN Study policies on publications and presentations by the professional participants in the study

To assure that all professionals involved with the Study know and understand the policies of the Study, and to preclude the possibilities of misunderstandings after initiation of the Study, each professional member will be given a copy of this Chapter and will be asked to sign a Statement of Understanding Form (see next pages) listing the major provisions of the Chapter and attesting to his/her acceptance of these policies. The original of the signed Statement of Understanding Form should be returned to the DCC for record purposes. The copies of the Chapter and the signed Statement of Understanding Form should be kept by the FHN professional participant for reference.

FHN STUDY

Statement of Understanding of Policy Concerning Publications and Presentations

To assure that all professionals involved with the FHN Study know and understand the policies of the FHN Study regarding publications and presentations, and to preclude the possibilities of misunderstandings after initiation of the Study, each professional member will be given a copy of the Manual of Operations Section 26 detailing these policies and will be asked to sign this form attesting to his/her acceptance of these policies, which are summarized below.

I. Material Covered by These Policies

All material to be presented orally or submitted for publication or dissemination by individuals associated with the FHN Study and dealing with any aspect of the FHN Study must receive prior review and approval by the Publications and Ancillary Studies (PAS) Committee with the following exception:

Material prepared for publicity purposes either nationally or within the recruitment region of a FHN Clinical Center, or presented orally or as handouts or posters to professional audiences solely for the purposes of informing the profession of the FHN Study and its objectives, need not be reviewed by the PAS Committee. Such material must be limited to a background discussion of the issue involved and a description of the FHN Study organization, objectives, and entrance criteria, and to results of the Study that have previously been presented to a scientific body or published in a scientific journal. It must not include discussion of any previously unrepresented or unpublished FHN Study outcomes or results, and must not itself result in publication of an abstract or other citable professional reference.

II. Assignment of Writing Committees for Publications

The PAS Committee will solicit volunteers for each writing committee for abstracts and publications and make a recommendation on the writing committee and topic to the FHN Steering Committee Chair. The FHN Steering Committee Chair will decide on the final composition and topic of the committee after consultation with the Chair of the PAS Committee. All interested individuals will be given a chance to request appointment to the various writing committees, but the final appointments will be by the Chair of the Steering Committee.

III. Authorship

The FHN policies specify the authorship for each of the four different classes of publication or abstract (See Section 26.5 of the Manual of Operations). These policies are binding and must be followed in all publications derived from the FHN Study.

IV. Review of Abstracts

All abstracts must be reviewed and approved by members of the PAS Committee before being submitted (See Section 26.10 of the Manual of Operations). These abstracts must be delivered to the

reviewers at least seven (7) days before the submission deadline to permit time for this review. Abstracts not approved in this fashion will be withdrawn by the FHN Study.

V. Review of Materials for Presentations

Approval for submission of an abstract does not automatically grant approval of the material ultimately to be presented. This material must also be submitted for review and approval by members of the PAS Committee at least seven (7) days prior to the scheduled oral or poster presentation.

VI. Review of Papers

All materials for which there is no explicit deadline, and all full papers that may result in a citable scientific reference, whether or not there is a deadline for submission, must be submitted to the Chair of the PAS Committee for formal review by the entire Committee (see Section 26.11 in the Manual of Operations). If there is a deadline for submission of a formal paper, it is the responsibility of the submitter to be certain that it is submitted to the Chair of the PAS Committee at least 30 days prior to the deadline, to permit such review.

VII. Certification by FHN Study Participant

This is to certify that I have read the above statement of policies of the FHN Study with regard to publications and presentations, understand it, and agree to abide by it in matters of all publications and presentations derived from the FHN Study.

(Signature)

(Date)

(Print or Type Name and Institution)