23. Publications and Presentations Policy

23.1 Group Definitions

HFM Study Investigators

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

1) HFM Study PIs
    a) HFM Study Principal Investigators at the Clinical Centers, Data Coordinating Center and Central Cores
    b) NIDDK Project Scientist
    c) Steering Committee Chair
2) HFM Study Investigators
    a) Typically, investigators who are at the Clinical Centers, Data Coordinating Center and Central Cores, other than *HFM Study Principal Investigators.*
    b) Research staff and study coordinators
    c) Trainees
        i) Trainees funded to maintain an active role on the HFM Study.
        ii) Students or fellows with an active but temporary role.
        iii) *HFM Study Principal Investigators* will be responsible for identifying *Trainees* at their sites annually or more often if changes in this group occur.
3) Ancillary Study Investigators
    a) Individuals who propose, receive approval from the PAS Committee, and obtain funding for an HFM ancillary study.

Publications and Ancillary Studies (PAS) Committee

The HFM PAS Committee will be chaired by the Steering Committee Chair. Other members are:

1) HFM Study PIs at the Clinical Centers
2) DCC PI
3) NIDDK Project Scientist

[Note: Above makes the PAS the same as the Steering Committee. PAS does not include Core PIs.]

23.2 Publication Policy Principles

1) Publication of scientific research papers is a central and critical aspect of the HFM Study because:
    a) Scientific publications will be the principal mechanism by which the HFM Study will communicate its scientific findings.
    b) Scientific publications represent one of the most important mechanisms for HFM Study Investigators to achieve scientific and academic recognition for their participation in HFM Study.
2) Research questions and hypotheses to be addressed using HFM 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.
    a) 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 I error and assessments of statistical significance.

b) 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 I error and assessments of statistical significance.

3) Publication policies should promote scientific inquiry within and productivity from the HFM Study.
4) 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).
5) Publication of scientific findings from the HFM Study should proceed in a timely fashion once relevant analyses are complete.
6) Abstracts, presentations, and publications based on HFM Study material must be accurate and objective and must not compromise the scientific integrity of the HFM Study.
7) The publications arising from the HFM Study should avoid overlap (except for review articles) and conflicting representation of HFM Study findings.
8) Recognition through authorship will be distributed among the *HFM Study Investigators* so that:
    a) *HFM Study PIs* have equitable opportunity to lead and co-author HFM Study publications.
    b) *HFM Study Investigators* have opportunity to lead and be co-authors on publications resulting from analyses made possible through their collaboration, and participate in publications reporting scientific findings to which they have contributed.
    c) *Ancillary Study Investigators* have the opportunity to lead and be co-authors on publications resulting from analyses made possible through their collaboration.
9) The HFM Study promotes the career development of trainees and junior faculty by providing them opportunity to lead and to be recognized as co-authors of HFM Study publications, as appropriate.
10) Authorship on HFM Study publications will adhere to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals of the International Committee of Medical Journal Editors.

To adhere to these principles, it is the policy of the Study that preparation of all publications or presentations, other than materials prepared for local publicity purposes (see Section 23.3), must be assigned by the Chair of the Publications and Ancillary Studies (PAS) Committee to specifically appointed writing committees. Materials must be reviewed and approved by the PAS Committee and/or the Steering Committee before publication or presentation.

23.3 Scope of Policy, and Exception for Local Informational Materials

All material to be presented orally, as poster, or submitted for publication for 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 with the following exception:

Material prepared for informational purposes within the recruitment region of a HFM Clinical Center, or presented orally or as handouts or posters to local 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 along with vascular access 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 study data not previously presented or published. Informational material for national dissemination, including lay summaries, does need to be reviewed and approved by the PAS Committee

23.4 Source of Suggestions for Publications of the Study

Suggestions for topics appropriate for preparation of abstracts or peer-reviewed papers are made by the PAS Committee. In addition, all investigators and staff in the Study are invited to suggest topics appropriate for preparation as abstracts and peer-reviewed papers 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, or planning to be assigned, to other writing committees. Where such overlap exists, the Chair of the PAS Committee may make recommendations that the suggestion be referred to an existing writing committee, that additional study investigators 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 Chair of the PAS Committee.

It is the intent of this policy 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 23.7.

It is also the intention of this policy to promote the conversion of as many abstracts as possible into full manuscripts and to discourage the production and presentation of abstracts that do not represent an intermediate step towards the preparation of a full scientific manuscript.

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.

23.5 Assignment of Writing Committees

Topics suggested for presentation or publication that do not overlap with an existing committee will be circulated to HFM Study PIs and HFM Study investigators. Writing committees should be formed with the intent of writing a paper for publication. This committee can also prepare abstracts for submission to professional meetings. Volunteers for the writing committee solicited are from all investigators. Persons are requested to suggest and justify names for lead authors (Chair of writing committees) and co-authors. This information will be collated and reviewed by the Chair of the PAS Committee and the DCC PI. The Chair of the PAS Committee will decide on the final composition of the writing committee.

If a topic is suggested by an investigator of the Study, and approved by the PAS, the writing committee will be formed as just described and 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 that ancillary 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 chairs will be made fairly to all professionals -- physicians, study coordinators, nurses, statisticians, and others -- in a manner that recognizes the unique contributions of each member of the Study to its performance. Any dispute about the selection of the lead author or co-author will be settled by the Chair of the PAS Committee. In all cases, writing committees requiring analysis of data by the Data Coordinating Center will have at least one 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.

23.6 Classes of Reports of the Study

There are four types of reports of the HFM Study:

A. Reports of the major outcomes of the Study. It is assumed that there will generally be only a few of these reports.

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 HFM 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 HFM publications. However, the Principal Investigator of an ancillary study should be assigned the prerogative and should take primary responsibility in publishing the results of the study.

23.7 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 HFM professional staff. Thus, reports of Types A and B must give recognition to all the investigators of the Study, and other Types must give primary recognition to those participating in the specific investigation. 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 HFM authorship policy attempts to recognize each of these goals. The authors of HFM Study publications will be listed as detailed below for each type of publication.

Type A publications:

Abstracts: the Hemodialysis Fistula Maturation (HFM) Study Group[1], presented by XXXX.

Papers: the Hemodialysis Fistula Maturation (HFM) Study Group[1], prepared by XXXX.

[1]The HFM participant box, detailed below, must be included in these papers. If a society's or journal's 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 Hemodialysis Fistula Maturation (HFM) Study Group[1]

[1]The HFM participant box will be included in all papers if this can be arranged with the publisher. Otherwise it will be referenced to 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 for the HFM Study

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

23.8 Listing of Professional Participants in the Participant Box

The HFM Study 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 or investigators 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:

Steering Committee Chair
Clinical Centers (in alphabetical order by center name)
DCC
Cores/Repositories
NIDDK

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.

23.9 Acknowledgement of Support

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).

23.10 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.

23.11 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 shall contact the Chair of the PAS Committee and the DCC P.I. should be contacted. The Chair (or designee) 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 (or designee) of their approval or disapproval. If there is unanimous approval, the PAS Committee Chair (or designee) shall inform (through the DCC) the submitter that he/she has 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.

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.

Also, if there is a meeting proceedings paper, the lead author must notify the PAS Chair at the time the abstract is proposed and receive approval for both abstract and the affiliated proceeding paper.

23.12 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 (including book chapters and reviews), 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 of the PAS Committee, shall appoint at least 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. The two primary reviewers shall each prepare and send to the Chair a written critique of the submitted material for distribution to the entire PAS Committee. The PAS Committee will be given a deadline by which any comments or critiques must be received by the Chair of the PAS Committee.

2) The Chair of the PAS Committee may schedule a conference call of the PAS Committee, to review papers and other non-time critical materials as agenda items. The reviews of the panel members and any comments received from the center PIs will be distributed to the committee with the agenda. Alternatively, the Chair can decide if the review can be done by email input, rather than by conference call.

3) While discussion of the submitted paper(s) and other materials will be led by the two appointed reviewers, all members of the PAS 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 (through the DCC) for communicating the decision of the Committee to the authors, together with a summary of suggestions for revision, if any.

6) In the event that editors of a scientific journal to which an approved HFM 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.

23.13 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 HFM 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 HFM 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.

23.14 Maintenance of Records of Publications and Presentations

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

1) Peer-reviewed accepted or published papers in professional journals
2) Abstracts published in citable journals
3) Presentations at regional, national or international meetings

This listing will be updated at least every six months and will be distributed to the all investigators in the Study, together with copies of any scientific papers or abstracts published since the last update.

This is intended to inform investigators of all study findings and to facilitate the updating of curricula vitae.

23.15 Acknowledgement and Acceptance of HFM Study Policies on Publications and Presentations by the Study Investigators

To assure that all investigators (the three groups defined in Section 23.1) involved with the Study are aware of the policies of the Study, and to minimize the possibilities of misunderstandings after initiation of the Study, each investigator (except vascular function personnel, sonographers) 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. A copy of the Chapter and their signed Statement of Understanding Form should be kept by each HFM investigator.

HEMODIALYSIS FISTULA MATURATION STUDY

Statement of Understanding of Policy Concerning Publications and Presentations

To assure that all professionals involved with the HFM Study know and understand the policies of the HFM 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 23 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 at meetings or submitted for publication or dissemination by individuals associated with the HFM Study and dealing with any aspect of the HFM Study must receive prior review and approval by the Publications and Ancillary Studies (PAS) Committee with the following exception:

Material prepared for publicity purposes within the recruitment region of a HFM Clinical Center, or presented orally or as handouts or posters to professional audiences solely for the purposes of informing the profession of the HFM Study and its objectives, need not be reviewed by the PAS Committee. Material for national dissemination does need to be reviewed and approved by the PAS Committee. Such material must be limited to a background discussion of the issue involved and a description of the HFM 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 unpresented or unpublished HFM 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 HFM Steering Committee Chair. The HFM PAS Chair will decide on the final composition and topic of the committee. All interested individuals will be given a chance to request appointment to the various writing committees, but the final appointments will be determined by the Chair of the PAS Committee.

III. Authorship

The HFM policies specify the authorship for each of the four different classes of publication or abstract (See Section 23.6 of the Manual of Operations). These policies are binding and must be followed in all publications derived from the HFM Study.

IV. Review of Abstracts

All abstracts must be reviewed and approved by the PAS Committee before being submitted (See Section 23.11 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 HFM 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 23.12 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 HFM Study Participant

This is to certify that I have read the above statement of policies of the HFM 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 HFM Study.

_____ _____

(Signature) (Date)

_____

(Print or Type Name and Institution)