MDRD Local Manual of Operations

Volume 3

Chapter 11

Publications and Ancillary Studies Committee

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Manual of Operations
Volume 3, Chapter 11
Publications and Ancillary Studies Committee

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Administrative Manual of Operations

Volume 3, Chapter 11

Publications and Presentations

11.1 Introduction

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

i. To assure timely publication of the results of the MDRD Study to the appropriate professional audiences,

ii. 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),

iii. To maintain high standards of quality of all material published by the MDRD Study,

iv. To guard against duplicate publication of results by assuring absence of overlap of materials prepared by various writing committees, and

v. To assure equitable attribution of credit to all of the professionals participating in the MDRD Study.

To accomplish these ends, it is the policy of the MDRD Study that preparation of all publications or presentations, other than materials prepared for local publicity purposes, must be assigned by the Study Chairman to specifically appointed writing committees, and that all such materials must be reviewed and approved by the Publication and Ancillary Studies (P&AS) Committee and/or the Steering and Planning (S&P) Committee before publication.

11.2 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 MDRD Study and dealing with any aspect of the MDRD Study must receive prior review and approval by the P&AS Committee/S&P Committee with the following exception:

Material prepared for publicity purposes either nationally or within the recruitment region of an MDRD Clinical Center, or presented orally or as handouts or posters to professional audiences

solely for the purposes of informing the profession of the MDRD Study and its objectives, need not be reviewed by the P&AS Committee. Such material must be limited to a background discussion of the issue of diet and blood pressure control as a treatments for progressive renal disease and a description of the MDRD 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 and unpublished MDRD Study outcomes or other citable professional reference.

11.3 Source of Suggestions for Publications of the MDRD Study

All participants in the MDRD Study are invited to suggest topics appropriate for preparation as abstracts, peer reviewed papers, or chapters and reviews from the MDRD Study. Such suggestions should be made to the Study Chair, with copies forwarded to the Chair of the P&AS 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 P&AS 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 rests with the Study Chair.

It is the policy of the MDRD 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 MDRD 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 11.6.

In addition, the P&AS 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 MDRD Study are reported to the scientific community in a timely fashion.

11.4 Assignment of Writing Committees

The Study Chair, upon receipt of a recommendation for preparation of a topic for publication, and after confirming that the topic does not overlap with a previous assignment to another writing committee, will appoint the chair of a new writing committee to prepare the publication. Appointments of writing committee chairmanships will be made in an equitable fashion to all professionals--physicians, dietitians, nurses, statisticians, and others -- in a fashion that recognizes the special contributions of each member of the MDRD Study to its performance.

Upon appointment of the Chair of a new writing committee, the Study Chair will notify each collaborating center, including clinical centers, the DCC, the NCC, NIH, HCFA, and the central laboratories, of the new writing committee, soliciting indications of interest to be on that writing committee. If more individuals express interest than it is practical to assign to a committee, the Study Chair shall make the final assignments of the members of the 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 Study Chair 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.

11.5 Classes of Reports of the MDRD Study

There are four classes of reports of the MDRD Study:

A. Reports of the major outcomes of the Study. It is assumed that there will generally be only one or two such all over reports derived from each Phase of the Study. Generally these reports will be prepared by the Executive Committee serving as the writing committee, with the Study Chair as the Chair of the writing committee.

B. Reports addressing in detail one aspect of the MDRD 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 MDRD Study, (e.g., substudies or ancillary studies), or originally conceived analyses of data from the entire MDRD Study (original analyses).

D. Reports of investigations initiated outside of the MDRD Study, but using data or samples collected by the MDRD Study. The investigators may be MDRD or other investigators, but the source of the ideas and the funding for the study will have been derived outside of the MDRD Study itself.

11.6 Authorship Policy

The authorship policy of the MDRD 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 MDRD professional staff. Thus, all reports, of whatever Type, must give recognition to all the participants of the MDRD Study, and reports of Types A and B must give primary recognition to the entire study professional staff. On the otherhand, 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 MDRD Study. The MDRD authorship policy attempts to recognize each of these goals. The authors of MDRD publications will be listed as detailed below for each type of publication.

Type A publications:

abstracts: from the Modification of Diet in Renal Disease Study, presented by XXXX. (This will usually by the Study Chair).

papers: from the Modification of Diet in Renal Disease Study[1]

1 The MDRD participant box, detailed below, must be included in these papers.

Type B publications:

abstracts and papers: from the Modification of Diet in Renal Disease Study[1], prepared by

[Chair of the writing committee, other members of the writing committee listed alphabetically][2]

[1] The MDRD 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.

[2] It will be stated in a footnote that the names of the writing committee are listed alphabetically after the name of the committees chair.

Type C and Type D publications:

abstracts and papers: by [members of the writing committee in any order acceptable to them] and the Modification of Diet in Renal Disease Study[1]

[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 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.

11.7 Listing of Professional Participants in the MDRD Participant Box

The MDRD participant box for each Phase will list all professionals that have participated in the MDRD Study for a minimum of one year in that Phase. 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 which he/she held in the study. The centers will be listed in the following order:

NIH

HCFA

Study Chair

DCC

NCC

Clinical Centers (in alphabetical order)

Central Laboratories (in alphabetical order)

Prior to the publication of any papers from any Phase of the MDRD Study, each center will

be asked to confirm and approve the listing of the personnel from that center in the MDRD Participant Box.

11.8 Acknowledgement of Support and Reprint Addresses

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

The Modification of Diet in Renal Disease Study is supported by the Division of Kidney, Urologic and Hematologic Diseases of the National Institute of Diabetes and Digestive and Kidney Diseases, NIH, through cooperative agreements. Additional support and technical assistance is provided by the Health Care Financing Administration.

The following information regarding reprint requests should be included in all papers prepared for the MDRD Study. The NKUD Clearing House will maintain an inventory of all MDRD Studies and will actually mail out the reprints.

Requests for reprints should be addressed to:

National Kidney and Urologic Diseases Clearing House
Box NKUDIC
Bethesda, MD 20892

11.9 Schedule for Completion of Writing Assignments and Resolution of Overlaps Between Writing Committees

At the time that a writing committee is constituted by the Study Chair, the P&AS 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 P&AS Committee a general outline of the proposed publication within a month of receiving its assignment, to permit the P&AS 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 P&AS 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 Study Chair. The Chair of the P&AS Committee will report at each meeting of the Operations Committee and the S&P Committee on the progress of the various writing committees.

11.10 Review of Abstracts and Presentations by the P&AS 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:

i. 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 P&AS Committee. In the event that the Chair is unavailable, the Alternate Chair may be contacted. The Chair (or Alternate Chair) will name a subcommittee of three members of the P&AS Committee to review the submitted material and will inform the submitter and this subcommittee of their appointment. The submitted material should be mailed by the submitter directly to these three reviewers so as to reach them no fewer than seven (7) days prior to the deadline for submission.

ii. 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 P&AS Committee Chair (or Alternate Chair) shall inform the submitter that he/she has MDRD Study approval for the submission. In the event of a split vote for approval, the issue will be reviewed by the P&AS Committee Chair (or Alternate Chair) with the Chair of the MDRD Steering & Planning (S&P) Committee (or in his unavailability with the Chair of the Operations Committee) whose decision will be binding.

iii. All materials submitted for approval in this fashion will be distributed by mail, together with notice of the disposition, to all members of the P&AS Committee and to the Chair of the S&P Committee. All approved materials will also be forwarded to the NIH Trail Coordinator, and for record purposes to the Principal Investigator of the Data Coordinating Center, and will be distributed to the entire membership of the S&P Committee at the next meeting of that Committee as an Appendix to the report of the P&AS Committee.

iv. In the case of abstracts or other similar written material, the entire material to be submitted must be sent by the submitter for review by the appointed subcommittee.

v. 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.

vi. 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 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 P&As Committee that reviewed the initial abstract.

11.11 Review of Papers by the P&AS 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 P&AS 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, P&AS Committee, at least 30 days prior to the deadline, to permit such review. This review will be conducted as follows:

i. The Chair, P&AS Committee, shall appoint a panel of three primary reviewers, two of whom must be P&AS Committee members, and one of whom may be any professional member of the MDRD Study Group with appropriate expertise. The Chair shall distribute the material to all members of the P&AS Committee and to the Principal Investigator of each center participating in the MDRD Study. The three 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 P&AS Committee. The P.I.s of the various clinical centers will be given a deadline by which P.I.s of the various clinical centers will be given a deadline by which any comments of critiques that study participants at their center may wish to make just be received by the Chair, P&AS Committee. This mechanism will assure that each professional participating in the MDRD 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.

ii. The Chair, P&AS 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.

iii. While discussion of the submitted papers and other materials will be led by the three appointed reviewers, all members of the Committee will be invited to participate and all shall vote on final disposition.

iv. 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.

v. The Chair, P&AS 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 S&P Committees at that time, pending revision and resubmission.

vi. If there is a recommendation for approval or [illegible] final disapproval of submitted material, or if there is a recommenda[illegible]sted by the author(s), the Chair, P&AS Committee shal[illegible]ting to the Executive Committee for final action. In t[illegible] the P&AS Committee and the author(s), the Chair, P&[illegible] copy of the submitted material and a summary critique to Executive [illegible]e chair of the writing committee shall be given an opportunity to submit a rebuttal.

vii. The authority to grant final approval for a formal scientific paper of the MDRD Study rests with the S&P Committee, or the Executive Committee in the interim between meetings of the S&P Committee would be disadvantageous.

viii. All materials submitted for approval in this fashion will be forwarded, together with notice of disposition, to the Chair of the S&P Committee. All materials receiving final approval by the Executive or S&P Committee will also be forwarded to the NIH Trial Coordinator, and for record purposes to the Principal Investigator of the DCC.

ix. In the event that editors of a scientific journal to which an approved MDRD scientific manuscript is submitted suggest or require revisions of the manuscript, the revised manuscript must be reviewed again by the P&AS Committee prior to resubmission in the same manner as described above. Generally the Chair will appoint the same reviewers that first read the paper to review the revision, and every effort will be made to expedite such repeat reviews.

11.12 Criteria for Review of Materials by the P&AS Committee

All materials submitted to the P&AS Committee will be reviewed for acceptability on two grounds:

i. Materials shall be evaluated for scientific accuracy, quality, importance, and style. The intent is to assure that all approved MDRD materials reflect well on the MDRD Study.

ii. 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 MDRD Study or compromise the eventual publication of MDRD 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.

11.13 Maintenance of Records of Publications and Presentations

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

i. Peer reviewed papers accepted and published in professional journals

ii. Invited editorials, reviews, chapters, and books

iii. Abstracts published in citable journals

iv. Other presentations at regional or national meetings which 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 MDRD 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.

11.14 Acknowledgement and Acceptance of MDRD Policies on Publications and Presentations by the Professional Participants in the MDRD Study

To assure that all professionals involved with the MDRD Study know and understand the policies of the MDRD 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 page) 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 MDRD professional participant for reference.

11.15 Outline for Submission of Ancillary Studies Proposals

To assure that proposals for ancillary studies to be undertaken in conjunction with the main MDRD Study protocol have adequate information to permit their evaluation, proposers are requested to submit such proposals in the following format:

I. Hypothesis to be tested.
Specific outcome variables that will be assessed

II. Significance of the proposed ancillary study.
Why it is necessary to perform this ancillary study within the context of the main Study?

III. How will performance of this ancillary study affect the main MdRD Study? Specifically:

a. Will there be any deviations from the main MDRD Study protocol? If so, what will they be?

b. How much additional patient, staff, DCC, and NCC time will be required to complete this ancillary study?

IV. What will be the cost of the ancillary study? This analysis should include costs of needed equipment, supplies, forms, nutritional analysis, statistical analysis, and personnel time.

V. Data analysis and quality control

a. What are the specific measurements that will be made? How frequently? On what group of patients?

b. How will the investigators assure the accuracy and precision of the data that is obtained?

c. What training of personnel will be required?

VI. What sample size will be required to get meaningful answers, and what assumptions have been made in the calculation of this estimate?

VII. What statistical methods will be used to analyze the resulting data?

VIII. What will be the precise protocol? Specify in detail.

MODIFICATION OF DIET IN RENAL DISEASE STUDY

Statement of Understanding of Policy
concerning Publications and Presentations

To assure that all professionals involved with the MDRD Study know and understand the policies of the MDRD 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 chapter of the Administrative Manual of Operations detailing these policies and will be asked to sign this form attesting to his/her acceptance of these policies, which are summarized here.

I. Material covered by these policies

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

Material prepared for publicity purposes either nationally or within the recruitment region of an MDRD Clinical Center, or presented orally or as handouts or posters to professional audiences solely for the purposes of informing the profession of the MDRD Study and its objectives, need not be reviewed by the P&AS Committee. Such material must be limited to a background discussion of the issue of diet and blood pressure control as treatments for progressive renal disease and a description of the MDRD 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 <u>not</u> include discussion of any previously unpresented and unpublished MDRD Study outcomes or results, and must <u>not</u> itself result in publication of an abstract or other citable professional reference.

II. Assignment of writing committees for publications

The MDRD Study Chair will appoint writing committees to prepare <u>all</u> abstracts and papers for the MDRD Study, and will specify the subject material to be dealt with by each writing 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 Study Chair.

III. Authorship

The MDRD policies specifies the authorship for each of the four different classes of publication or abstract (See Administrative Manual of Operations, Volume III, Chapter 9.5 and 9.6) These policies are binding and must be followed in all publications derived from the MDRD Study.

IV. Review of Abstracts

All abstracts must be reviewed and approved by members of the Publications and Ancillary Studies (P&AS) Committee before being submitted. 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 MDRD 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 P&AS Committee at least seven (7) days prior to the scheduled oral or poster presentation.

V. 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 P&AS 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, P&AS Committee, at least 30 days prior to the deadline, to permit such review.

VI. Certification by MDRD Study Participant

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

_____ _____

(Signature) (Date)