



The Nephrotic Syndrome Study Network Publication Policy

Submit publications for review to: NEPTUNE-Pub-Review@umich.edu

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NEPTUNE Publication Policy

I. Overview

- A. The success of the NEPTUNE Study primarily depends on the quality and number of its scientific publications and presentations. This policy provides guidelines to ensure appropriate use of the NEPTUNE data, timely completion of manuscripts and presentations, equitable access to authorship, and adherence to established principles of authorship.
- B. “NEPTUNE Investigators” may submit requests to lead a manuscript to the NEPTUNE Publications Committee, with final approval by the NEPTUNE Steering Committee, utilizing NEPTUNE data, pursuing research questions not otherwise approved as the focus of prior manuscript proposals or as specific aims of approved Ancillary Studies.
- C. For the purposes of this policy, “NEPTUNE Investigators” are all individuals affiliated with the NEPTUNE Study to whom this policy will apply. The NEPTUNE Investigators are categorized into four groups:
 1. NEPTUNE PIs
 - a. NEPTUNE Principal Investigators
 - b. NIDDK Project Scientists
 2. NEPTUNE Core Investigators
 - a. Typically, but not necessarily limited to, investigators who are Key Personnel at the NEPTUNE Sites and the Data Analysis and Coordinating Center (DACC) [other than NEPTUNE PIs], including PIs of Histopathology Reading Centers and Laboratories.
 - b. NEPTUNE PIs will be responsible for identifying the NEPTUNE Core Investigators at their sites annually or as often as changes in this group occur.
 3. NEPTUNE Team Members
 - a. 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 NEPTUNE investigators who left the study, consultants).
 - b. Research staff
 - c. Trainees, including funded career development awardees and students or fellows with an active but temporary role. NEPTUNE PIs will be responsible for identifying Trainees at their sites annually or more often if changes in this group occur.
 4. Ancillary Investigators
Individuals who receive approval for a research project utilizing NEPTUNE resources

II. Publication Policy Principles

- A. Publication of scientific research papers is a central and critical aspect of the NEPTUNE Study because:
 1. Scientific publications will be the principal mechanism by which the NEPTUNE Study will communicate its scientific findings.
 2. Scientific publications represent one of the most important mechanisms for NEPTUNE Investigators to achieve scientific and academic recognition for their participation in NEPTUNE.

- B. Research questions and hypotheses to be addressed using NEPTUNE Study data should be formulated a priori and clearly stated in a manuscript proposal (see Section IV) to reduce the likelihood that study results are attributable to type I error.
 - 1. 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.
 - 2. 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. This Publication Policy is meant to promote scientific inquiry within and productivity from the NEPTUNE Study.
- D. Publication of scientific findings from the NEPTUNE Study should proceed in a timely fashion once relevant analyses are complete.
- E. Abstracts, presentations, and publications based on NEPTUNE material must be accurate and objective and must not compromise the scientific integrity of the NEPTUNE study.
- F. The publications arising from the NEPTUNE Study should avoid overlap and conflicting representation of NEPTUNE Study findings. It is a responsibility of the NEPTUNE Publications Committee to manage potential overlap.
- G. Recognition through authorship will be distributed among the NEPTUNE Investigators so that:
 - 1. All NEPTUNE PIs have equitable opportunity to lead and co-author NEPTUNE publications;
 - 2. All NEPTUNE Core Investigators have the opportunity to lead and co-author NEPTUNE publications;
 - 3. All NEPTUNE Team Members have the opportunity to participate in publications reporting scientific findings to which they have contributed;
 - 4. All NEPTUNE Team Members have the opportunity to lead and be co-authors on publications resulting from analyses made possible through their collaboration;
 - 5. All Ancillary Investigators have the opportunity to lead and be co-authors on publications resulting from analyses made possible through their collaboration.
- H. The NEPTUNE Study promotes the career development of trainees and junior faculty by providing them the opportunity to lead and to be recognized as co-authors of NEPTUNE publications. This policy provides a framework for balancing career development considerations against the legitimate interests of NEPTUNE PIs and NEPTUNE Core Investigators to lead NEPTUNE publications, via formation of the Writing Committees.
- I. Authorship on NEPTUNE publications will adhere to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals of the International Committee of Medical Journal Editors.

III. Structure of the Publications Committee

- A. The Publications Committee will be composed of NEPTUNE Investigators, who have expressed interest in this activity. A NIDDK representative and members of the DACC are also included.
- B. Implementation of this Publications Policy and management of day-to-day activities will be the responsibility of the NEPTUNE Publications Committee Chairs.

- C. The DACC will provide staffing for the NEPTUNE Publications 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. Send all communications for the NEPTUNE Publications Committee to NEPTUNE-Pub-Review@umich.edu.

IV. Procedures for Manuscripts, Abstracts and Presentations

A. Manuscripts General Procedures

1. A manuscript proposal will be submitted to the Publications Committee for review (see Section VI for details on proposal submission), regardless of where analysis (central or local) will occur.
2. The Publications Committee will review all manuscript proposals to determine overlap with other papers or abstracts in process. In cases of 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 NEPTUNE web site. In addition, the Publications Committee will categorize the proposal as described below in Section IV D.
3. Upon approval by the Publications Committee, the DACC will assign a manuscript number to the proposal and log it into a tracking system. After approving the manuscript, the Publications Committee will name the Writing Committee Chair and constitute a Writing Committee (see Section V for details).
4. The Publications Committee, in consultation with the DACC, will determine priorities for DACC data analyses required for manuscripts and abstracts. However, preparation of manuscripts for which the data analyses do not occur at the DACC may start as soon as the Publications Committee gives approval and the DACC is able to provide the data needed for analysis.
5. Any investigator submitting a manuscript proposal agrees to the NEPTUNE internal data sharing policy (see below). Concurrence with these provisions occurs de facto with participation in a writing group. The data sharing policy will be included with Publication Committee approvals.

I agree to the following conditions regarding the use and disclosure of any NEPTUNE Study data I receive from the NEPTUNE Data Analysis Coordinating Center (DACC):

- a. I will not use or further disclose NEPTUNE data for any purpose other than accomplishing the approved scientific aims for which I will be conducting analyses.
- b. I will abide by all requirements of the NEPTUNE Publications and NEPTUNE Ancillary Studies policies with regard to the use and disclosure of any NEPTUNE data.
- c. I will implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality and integrity of any NEPTUNE data as well as prevent its inadvertent use or disclosure.
- d. I agree to return or destroy any NEPTUNE data I receive upon completion of analysis (e.g., defined by the acceptance of the manuscript reporting my findings) or at the end of any mandatory period of data archiving at my institution.

6. The DACC will maintain records indicating the distribution of authorship by individual and location.

B. Changes in Scope of Approved Manuscripts

1. 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 Publications Committee for approval. The Publications Committee will review all proposed changes and may nominate additional coauthors.
2. 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 Publications Committee for their approval. In general, the Writing Committee members will remain the same for both papers but the author order may be modified to share the lead and senior author roles among co-authors.
3. 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 Publications Committee for their approval.

C. Schedule for Manuscript Preparation

1. Draft

- a. Writing committees should complete a first draft within 4-6 months after receipt of a set of complete analyses from the DACC. If analysis is occurring in an extramural site, communication with the DACC should include expected timeline for data analysis and draft preparation. A first draft will consist, at a minimum, of Introduction, Methods, and Results Sections.
- b. 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.

2. Penultimate Draft

- a. The penultimate draft becomes due no later than 8-10 after the first draft is distributed to the Writing Committee.
- b. The penultimate draft should include:
 - i. A title with the acronym "NEPTUNE," whenever possible.
 - ii. "The NEPTUNE Investigators" as part of the list of authors, whenever possible.
 - iii. All grants (and grant numbers), which supported the work, should be acknowledged.
 - iv. This acknowledgment statement must also be included:

Acknowledgment:

The Nephrotic Syndrome Study Network Consortium (NEPTUNE), U54-DK-083912, is a part of the National Institutes of Health (NIH) Rare Disease Clinical Research Network (RDCRN), supported through a collaboration between the Office of Rare Diseases Research (ORDR), NCATS, and the National Institute of Diabetes, Digestive, and Kidney Diseases. Additional funding and/or programmatic support for this project has also been provided by the University of Michigan, the NephCure Kidney International and

the Halpin Foundation. The views expressed in written materials or publications do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention by trade names, commercial practices, or organizations imply endorsement by the U.S. Government.

PowerPoint presentations are to include a slide with the statement above and the logos of NCATS Rare Diseases Clinical Research Network, NIDDK, NEPTUNE, the NephCure Kidney International. The slide may be requested from NEPTUNE-Pub-Review@umich.edu.

- c. 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 to the Publications Committee.

3. Review

The NEPTUNE Steering Committee and the Publications Committee will simultaneously be given access to the penultimate draft manuscript for approval prior to submission to the journal. Members of both committees will be given one week to comment, with comments provided to the Writing Committee Chair who will decide if this input should lead to modification in the penultimate manuscript prior to submission.

4. Submission to a Journal

- a. The manuscript should be submitted to a journal as soon as comments from the Publications and Steering Committees are considered.
- b. At the time of submission, the lead author should determine if the journal will make the [final published version](#) of the article available in PubMed Central (PMC) no later than 12 months after publication without author involvement. If not, the author will need to request that the article be uploaded in the public domain, in order to comply with NIH requirements.
- c. NEPTUNE-Pub-Review@umich.edu, the DACC, and all co-authors must receive a copy of the journal cover letter and final submitted version of the manuscript.

5. Deviations from Schedule

- a. Deviations from this schedule require approval from the Publications Committee.
- b. Failure to adhere to this schedule will prompt a review of circumstances.
- c. 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 and/or reconstituting the writing committee.

6. Tracking Manuscripts

- a. The Writing Committee Chair must keep the Publications Committee and the co-authors informed as to the manuscript's progress through journal review.
- b. The Writing Committee Chair must also send a copy of the journal's letter of acceptance, request for revisions, or letter of rejection to NEPTUNE-Pub-Review@umich.edu.
- c. All NEPTUNE publications fall under the open access policy and must communicate the NIH Manuscript Submission System reference number (NIHMSID) or PMCID.

- d. Upon publication of the manuscript, the Writing Committee Chair must provide either a reprint or copies of the final publication to NEPTUNE-Pub-Review@umich.edu.
- e. If there are substantive changes made in the manuscript during journal review (including but not limited to adding new data, re-analyzing the existing data set used for the initial submission, major findings or conclusions, alterations of the sample set, exclusion/inclusion of major covariates, etc.), an outline of the proposed revisions should be submitted to the Publications Committee for re-review. Publication Committee review will primarily focus on overlap with other manuscripts in process and burden to the DACC. If the change requires new acquisition of biospecimens, or use of already acquired biospecimens, the request will be reviewed by the DACC and the Ancillary Studies Committee. Manuscript revision should commence after Publication Committee concurrence with requested changes.

D. Types of Manuscripts

1. Core Study Manuscripts

- a. Core Study Manuscripts analyze data collected as part of the Core NEPTUNE data set, and directly derive from the NEPTUNE Core study aims as described in the NEPTUNE Study Protocol. The Core NEPTUNE data set consists of all data collected as part of the NEPTUNE Study annual award from the NIH to the DACC and NEPTUNE sites, data collected through NIH-funded supplements to these awards, and data collected through other supplemental funding to the NEPTUNE Study (e.g. funding from industry, NGOs). In addition, it is recognized (see the NEPTUNE Ancillary Study Policy) that data collected under the auspices of a formally approved NEPTUNE Ancillary Study will become part of the Core NEPTUNE data set once collected and their analysis related to the Ancillary Study aims has been completed in accordance with the NEPTUNE Ancillary Studies Policy.
- b. Core Manuscripts are formally identified by the Publications Committee, though nominations can come from the Steering Committee, Working Groups and/or the DACC. This list is subject to review and formal approval by the Steering Committee. The DACC will maintain the approved list of Core Manuscripts. The Publications Committee will coordinate initiation of Writing Committees with the DACC to develop these manuscripts.
- c. Authorship on Core Manuscripts:
 - i. The masthead on core manuscripts will represent each NEPTUNE site. Each site will include one PI from Cohort A and one PI from Cohort B (if appropriate). Each site will be responsible for determining the investigator/author to be included. The appendix will include all investigators and research staff.
 - ii. The masthead on core manuscripts may include additional authors per site. Additional authors per site will be based on the number of actively enrolled participants at the site:
 - 1 author for first 10 patients actively enrolled (not screen ineligible)
 - 2 authors for sites with 11-39 enrolled
 - 3 authors for sites > 40

Each site will be responsible for determining the investigator/author to be included. In terms of authorship order on core manuscripts, the writing committee authors are listed first, and they determine who serves as senior author and the order of the

rest of the committee. All other authors are listed after the writing committee, in alphabetical order.

- iii. The Histopathology Committee will be considered as its own site and will be represented on core papers. Core pathology data is considered as the pathology data proposed in the original grant application –the histopathological diagnosis. Special activities within the histopathology committee, such as digital pathology and descriptors are considered as ancillary. As with all ancillary study data, ancillary pathology data will become core data two years after publication unless the dataset continues to be developed.
- iv. The DACC will be considered their own site and will be represented on core papers. The DACC will have three slots on core manuscripts, but will utilize these slots only as needed. Distribution of DACC slots among DACC members will be decided on a project-by-project base but ensuring adequate representation and rotation among DACC members.

2. Ancillary Study Manuscripts

- a. Ancillary Study Manuscripts are defined as 1) manuscripts that result from approved NEPTUNE Ancillary Studies or 2) manuscripts proposed in concept sheets that are not directly supporting NEPTUNE core grant aims. Manuscripts from approved ancillary studies are based primarily on data elements originating from the specific aims of those studies. See NEPTUNE Ancillary Studies Policy on the definition of an Ancillary Study.
- b. Supplemental data made possible by funding that is awarded to “the NEPTUNE Study” (e.g. in the form of industry grants) rather than to an individual investigator will be considered, “core NEPTUNE data.”
- c. Ancillary Study Manuscripts are subject to the same review and tracking procedures as Core Manuscripts.
- d. Ancillary Study Manuscripts will be tracked centrally for progress as described for Core Manuscripts before submission to a journal.

E. Abstracts and Presentations

1. Preparation and Submission of **Abstracts** for Scientific Meetings

- a. No abstracts may be submitted to any national or international organization for consideration without prior notification and approval by the NEPTUNE Publications Committee and signoff from all co-authors.
- b. Concept sheets should be used to propose NEPTUNE abstracts. Any abstracts requiring data analysis by the DACC must be approved before the DACC can honor such requests.
- c. The DACC requires at least four (4) weeks to prepare data for use in proposed abstracts or presentations. If necessary, prioritization of requests will be made depending upon other NEPTUNE-related DACC commitments. The proposing investigator(s) will be notified promptly if the DACC commitments exceed the ability to complete the requested analysis or data extraction.
- d. An investigator who submits an abstract without these approvals may be asked to withdraw the abstract or presentation in question.

- e. If a Writing Committee has been assembled for abstract preparation, it is encouraged that all writing committee members be identified as an author of that abstract, whenever possible.

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

- f. Regardless of the need for DACC data analysis, Writing Committee Chairs are required to obtain Publication Committee approval for abstracts prior to submission [see below].
- g. 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.
- h. 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 NEPTUNE authorship.
- i. The full text of abstracts is due to the Publications Committee for review no less than two weeks before the abstract submission deadline. Abstracts submitted with less lead time to submission dates may not be approved.
- j. Copies of accepted abstracts or invited presentations (including tables and graphs) must be submitted to the Publications Committee within two (2) weeks following the presentation to allow accurate documentation of NEPTUNE productivity.
- k. It is the intention of this policy to promote the conversion of as many abstracts as possible into full manuscripts. However abstract approval does not imply approval for manuscript. Approved abstracts must be followed up with full manuscript proposals.

2. Principles and Guidelines for NEPTUNE **Presentations**

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

- a. Presenters are encouraged to freely present NEPTUNE data, which have been published or are “in press.” NEPTUNE should be acknowledged in these presentations.
- b. Distribution of written handout material containing NEPTUNE data that have **not** been published is prohibited.
- c. Presenters who have questions about unpublished material that they would like to present must seek approval from the NEPTUNE Steering Committee (not the Publications Committee).
- d. Presentation of ancillary data from NEPTUNE must adhere to these guidelines.
- e. Slide presentations given for regional, national and international audiences will be made available on the NEPTUNE internal website.

V. Formation of Writing Committees

The Publications Committee will provide oversight in the process of convening Writing Committees and for nominating the Chairs of these Writing Committees. A Chair of the Publications Committee will receive nominations for chairs of writing committees from Publications Committee members and other NEPTUNE Investigators before proposing a Writing Committee Chair to the full Publications Committee. Selection

of a Chair of a Writing Committee will require a majority of affirmative votes from Publications Committee members.

A. General Principles for Selection of Writing Committee Chairs

1. While the following principles apply to both types of NEPTUNE Study manuscripts, ordinarily the individual proposing a Core Manuscript and the principal investigator of a NEPTUNE Ancillary Study will serve as the Writing Committee Chairs for Core and Ancillary manuscripts, respectively.
2. The Publications Committee will consider the following principles when selecting Writing Committee Chairs, in particular, for Core Manuscripts.
 - a. Equitable access to leadership of Writing Committees as delineated in Section I Publication Policy Principles.
 - b. Expertise of proposed Writing Committee chair based on prior publications and interest as demonstrated through ancillary study proposals, etc.
 - c. Proposed Writing Committee chair's available time and commitment to moving manuscript development forward.
 - d. To assist in selection when more than one candidate to chair a Writing Committee is identified, a priority ranking can be used as follows: first – NEPTUNE PIs, second – NEPTUNE Core Investigators, and third – NEPTUNE Team Members. This priority ranking is only a rough guide and the Publications Committee need not adhere to it explicitly if there are other considerations specified in this policy that dictate otherwise.

B. General Principles for the Selection of Writing Committee Members

1. The principles for selection of Writing Committees recognize that the NEPTUNE Study will generate many manuscripts.
2. The development of the NEPTUNE Study aims dictated a large number of Core Manuscripts, for which a broad constituency of NEPTUNE Investigators will have interest in authorship.
3. 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.
4. 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 – NEPTUNE PIs, second – NEPTUNE Core Investigators, and third – NEPTUNE 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.
5. The Writing Committee Chair, in collaboration with the Publications Committee, will work to identify potential Writing Committee members from among interested NEPTUNE 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 Publications Committee. Nomination to serve on a Writing Committee does not guarantee co-authorship. At least one member of the DACC will have membership on

each Writing Committee and a liaison from the DACC will work with each Writing Committee to facilitate the process and interactions with the DACC.

C. Process for Formation of Writing Committees for both Types of NEPTUNE 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 NEPTUNE investigators, widespread representation of NEPTUNE sites whenever appropriate and feasible, and inclusion of content-area experts throughout the NEPTUNE study network. To achieve these goals, the following steps are outlined:

1. Once a Core Manuscript proposal has been approved by the Publications Committee, the DACC will send an email to solicit interest in being included in the writing group to all NEPTUNE Core Investigators who were not already nominated by the manuscript proposal writer.

For Core NEPTUNE manuscripts, opportunities for authorship will be open to all NEPTUNE PIs, NEPTUNE Core Investigators, and NEPTUNE Team Members, who identifies their intention to fulfill the criteria for authorship in the Uniform Requirements (see separate document – Uniform Requirements for Manuscripts Submitted to Biomedical Journals, October 2018). The lead investigator will propose a writing committee and submit a concept sheet. The Publications Committee will review and approve the writing committee and concept sheet. Additional consortium members may be added upon request by the DACC or the Steering Committee. The writing committee will propose author order of the writing committee.

2. Once an Ancillary Manuscript proposal has been approved by the Publications Committee, the DACC will send an email to solicit interest in being included in the writing group to all NEPTUNE Core and Ancillary Investigators who were part of the original Ancillary Study proposal but who were not yet nominated by the manuscript proposal writer.
 - a. For Ancillary Manuscripts, opportunities for authorship will be open to all NEPTUNE PIs, NEPTUNE Core Investigators, and NEPTUNE Team Members, based at NEPTUNE sites participating in data collection for the related Ancillary Study, as well as to other qualifying investigators who identify their intention to fulfill the criteria for authorship in the Uniform Requirements (see separate document – Uniform Requirements for Manuscripts Submitted to Biomedical Journals, October 2018).
 - b. NEPTUNE PIs, NEPTUNE Core Investigators, and NEPTUNE Team Members based at NEPTUNE sites **not** participating in relevant ancillary data collection (for Ancillary Manuscripts) as well as other Ancillary Investigators (for Ancillary and Core Manuscripts) will qualify to request authorship depending on 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 separate document – Uniform Requirements for Manuscripts Submitted to Biomedical Journals, October 2018).
3. After two weeks have elapsed all nominations will be compiled and presented to the Publications Committee for deliberation and decision-making. Inclusion in the Writing Committee will depend principally on representation of sites, 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.

4. Principles to be used by the Publications Committee to guide achievement of adequate representation of NEPTUNE Core and Ancillary investigators in writing groups:
 - a. For NEPTUNE Study papers not directly addressing a specific aim from an Ancillary Study, representation if possible, of all NEPTUNE sites with voting rights (NEPTUNE sites, the NIH, and the DACC), at which individuals indicate an interest and commitment.
 - b. For NEPTUNE Study papers directly addressing a specific aim from an Ancillary Study, representation, if possible, of all NEPTUNE sites involved in data collection for an Ancillary Study, the NIH, and the DACC at which individuals indicate an interest and commitment.
 - c. Inclusion of representatives from core laboratories, when appropriate.
 - d. Writers of manuscript proposals may include non-NEPTUNE researchers who bring particular expertise in a topic. Basis for inclusion will need to be clearly stated.
 - e. Publications Committee will consider these potential authors, respecting the primary goals of the writing selection process.
 - f. Multiple roles and a broad scope of activities related to a manuscript by investigators at one or more NEPTUNE site or the DACC will often justify multiple authors from those centers.
5. Writing Committee rosters endorsed by the Publications Committee will be circulated to Steering Committee voting members, who will have one week to provide comments or feedback.
6. The entire process described above will typically take place during the period of one month following manuscript approval by the Publications Committee.
7. NEPTUNE-wide authorship stratified by each NEPTUNE entity (DACC, NEPTUNE sites (with coordinator representation), Reading Centers, Laboratories, NIDDK) will be reviewed at least three times per year and presented to the Steering Committee.

D. Writing Committee Responsibilities

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 Publications Committee;
 - b. 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.
 - c. Preparation and circulation of drafts for approval by each member of the writing committee before submission of a penultimate draft to the Publications 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 DACC and the Publications Committee, responses to the Publications Committee and NIDDK reviews, and to journal editors.

2. Writing Committee Members are responsible for performance of tasks assigned by the Chair within the allotted time.
 - 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 Publications 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 Project Executive Committee.

VI. Information Required for Proposal Submission

Proposals for manuscripts likely will arise from a number of sources including, but not limited to, the NEPTUNE Publications Committee, or working groups, and the NEPTUNE Investigators. A proposal from a NEPTUNE Clinical Site requires approval by that Center's Principal Investigator before submission to the Publications Committee. Those who propose scientific papers must present these formally to the Publications Committee. The proposal must include "Summary Information" and a brief description of "Proposal Details."

A. Summary Information

1. Proposal Title
2. Proposed Writing Committee (Including NEPTUNE investigator sponsor if first author is not a NEPTUNE Investigator)
3. Structured Abstract and Brief Description includes: hypothesis, rationale, methods and anticipated results
4. Type of Manuscript (Core, Ancillary, Pilot Study, Title & PI for Ancillary and Pilots)
5. Additional Comments

B. Proposal Details

1. Introduction (Brief rationale and background)
2. Research Hypothesis (Clear statement of scientific questions to be addressed)
3. Data (List of variables to be used)
4. Analysis plan and methods in consultation with the DACC (Detailed description of proposed statistical analyses)