**AlcHepNet**

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| *AlcHepNet*  **An NIAAA Funded Alcoholic Hepatitis Clinical, Translational, and Basic Research Network**        **Presentations and Publications**  **Policy** |

October 2019

**AlcHepNet Presentations and Publications Policy**

**Preamble:**

The AlcHepNet is consortium of Clinical Center Investigators, Translational Studies Investigators, Basic Science Investigators, and Pilot Studies Investigators. Each of these categories have separate and clearly identifiable funding from the NIAAA, as part of the AlcHepNet Consortium.

**Overarching Principles:**

**Papers resulting from the Clinical Trial and the Observational Study:** Primary stakeholders are the Clinical Center PIs and their co-investigators as well as the IU DCC. Other members of the AlcHepNet are eligible to submit a publication proposal for avail material from the Clinical Trial and the Observational Study, but it needs to be sponsored by one of the Clinical Center PIs. These proposals and resulting drafts would need to be reviewed by the AlcHepNet Presentations and Publications (P&P) Committee.

**Papers resulting from the Translational Studies:** TranslationalPIs are the primary stakeholders. By definition, AlcHepNet translational studies are based on biosamples collected from the Clinical Studies conducted by the AlcHepNet Clinical Investigators. Since it would not be possible to credit all clinical center PIs on the masthead, translational papers should consider “modified conventional authorship” (e.g., Rebecca Smith, John Smith, Robert Redford,…, and the AlcHepNet Clinical Centers Investigators). In selected instances, instead of modified conventional authorship, conventional authorship may be appropriate where one or more clinical center investigators may be placed as co-authors if there was a custom collection of samples, or other specific collaborations. Translational papers need to be reviewed by the AlcHepNet Presentations and Publications (P&P) Committee.

**Papers from Basic Science Grants:** PIs are the primary stakeholders and in generally papers stemming from the AlcHepNet basic science grants are outside the scope of this committee.

**Papers from Pilot Projects:** PIs are the primary stakeholders and in general, papers stemming from the AlcHepNet pilot grants are outside the scope of this committee.

# Charge of the Presentations and Publications Committee

The purpose of the Presentations and Publications (P&P) Committee is to oversee and provide guidance relative to reporting study data and to assure that study reports have expert input, a high standard of scientific quality, responsible conclusions, sound interpretations, and fulfill the overall objectives of the AlcHepNet. The charge of the P&P Committee is to:

* Develop and maintain the policy for publications in regards to: proposal of manuscripts, review and approval of manuscript proposals, assignment of tasks in analysis and writing, review of manuscripts, authorship policy, and other issues related to publications
* Develop the policy for presentations in regards to: proposal of presentations, review and approval or presentation proposals, assignment of tasks in analysis and writing, review of presentations, authorship policy, and other issues related to presentations
* Make recommendations to the Steering Committee about topics for publications
* Make recommendations to the Steering Committee about topics for presentations at national and international meetings
* Make recommendations concerning the priority and sequential order of submission of manuscripts and presentations
* Review investigator-initiated proposals for publications and presentations and make recommendations for approval or disapproval to the Steering Committee based on factors such as anticipated value to the scientific community, overlap with other papers, and appropriateness of the proposed writing committee
* Review manuscripts and recommend changes to the writing committee and then review revised manuscripts before submission
* Mediate and settle all disputes and conflicts among study investigators over publication or presentation priorities, authorship, and any other issues related to publications or presentations. Investigators who perceive inequities in authorship or other problems relating to authorship should discuss these concerns with the P&P Committee chairperson; if the difficulty cannot be settled in this informal manner, the concerned investigator should submit a letter to the P&P Committee chairperson outlining the problem. The document will be reviewed and discussed by the P&P Committee, and a written reply will be made to the investigator. If P&P Committee deliberations fail to resolve such a dispute, the dispute will be submitted for resolution to the full Steering Committee, excepting those with a conflict of interest
* Prepare and maintain a list of concepts for publications and prepare and maintain a list of approved NASH CRN publications, which shows the status of each manuscript from initiation through publication

The purview of the P&P Committee includes publications and presentations arising from AlcHepNet Clinical Studies, Already Funded Translational Studies, and Ancillary Studies developed on clinical and biosample material collected from the primary clinical studies. Basic research studies conducted by individual grantees are outside the scope of this committee unless requested on an Ad Hoc basis by the Steering Committee

# Goals

* To promote timely, scientifically accurate, and high-quality presentation and publication of findings from AlcHepNet studies
* To support broad and equitable participation by AlcHepNet investigators in presentations and publications
* To define a set of equitable policies and procedures to determine authorship and the order in which authors are listed
* To review and select topics for publications and presentations, assign authors to writing groups, set priorities for publications and presentations, and monitor progress of publications and presentations
* To provide editorial support and timely review for presentations and publications
* To defend the academic freedom of AlcHepNet investigators collectively to publish results emanating from the AlcHepNet studies
* To impose limitations if needed on publication of results from any center(s) that could threaten the integrity of collective data

# Scope

* These policies and procedures apply to original manuscripts (including methodology, validation, laboratory approaches), abstracts, oral and poster presentations, letters to the editor, meeting proceedings, and extended abstracts that include data collected as part of AlcHepNet clinical and translational studies.
* These policies and procedures apply to publications and presentations arising from AlcHepNet clinical and translational studies.
* The P&P Committee will propose amendments to the presentations and publications policy and procedures to the Steering Committee as necessary to clarify their intent

# Presentations and Publications Committee Membership

* The P&P committee consists of two co-chairs (one from Clinical Centers and one from Translational Centers), 3 clinical center principal investigators, 3 translational center principal investigators, one investigator from the IU DCC, one investigator from the UMass DCC, and an NIAAA representative. Chairs and members can be nominated by AlcHepNet members and are approved by the Steering Committee.
* The Chairpersons may be appointed on a rotational and a staggering fashion. One or both Chairpersons may be reappointed with no term limits.
* The members from the Data Coordinating Centers and NIAAA serve for the duration of the AlcHepNet unless there are personnel changes.
* The number of consecutive or interrupted terms that a chairperson or other elected member may serve will not be limited
* Each member has one vote.
* If a member is an author on a proposal, manuscript, or presentation or otherwise has a conflict of interest, the member will recuse himself/herself from voting on the proposal, manuscript, or presentation

# Definitions and Types of publications

* **Publication Proposal:** Proposal to obtain data that are already existing to put together an abstract or a full length manuscript. Additional analyses of the existing data may be needed, but not new tests or assays.
* **Primary papers** arise from main studies and address the main objectives of main studies or report primary outcome data or design and methods of main studies.
* **Secondary papers** arise from main studies and address secondary objectives of main studies or report data or design issues or methods that are more peripheral to the main studies than those addressed in main reports
* **Exploratory papers** arise from posthoc analyses of the main studies.
* **Ancillary study papers** arise from approved ancillary studies to the AlcHepNet. By definitions, primary and secondary objectives of the funded translational studies are NOT considered ancillary studies, but they are considered primary studies. Ancillary studies are new studies proposed by either AlcHepNet investigators or their collaborators and they are based on material collected by the AlcHepNet primary studies.
* Abstracts, meeting proceedings, extended abstracts, oral and poster presentations
* Letters to the editor

# Writing groups and authorship issues

## Writing groups

* Writing groups: The writing of manuscripts will reside with a writing group consisting of AlcHepNet investigators, one of whom will be designated the Chair. Investigators proposing manuscripts specify writing group membership on the proposal form. An investigator proposing a manuscript is not assured lead authorship on that manuscript.
* Investigators proposed to be writing group members must agree to participate in the writing group and must receive all drafts and comments as manuscripts and/or abstracts are developed

## Authorship criteria

* Authors should participate in the writing of the paper according to guidelines of the International Committee of Medical Journal Editors (see [http://www.icmje.org/recommendations/,](http://www.icmje.org/recommendations/)
* Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals,” updated December 2018).
* Those who participated in conception and design, analysis and interpretation of data, drafting the manuscript, critical revision of the manuscript relating to important intellectual content, and final approval of the manuscript should be included as authors. Expertise (e.g., statistical, virology, or pathology) that relates directly to the conduct of the study is an additional criterion for authorship
* Provision of study material or patients; data collection and assembly; administrative, technical, or logistic support; and obtaining funding do not necessarily merit authorship but should be considered on a case-by-case basis, especially when other contributions are included
* Honorary authorship will not be considered

# Authorship format by type of report

**Clinical Studies**

* Main reports will have modified conventional authorship (Name1, name2, ..., for the AlcHepNet Clinical Centers). An appendix listing all investigators of the AlcHepNet Clinical U01 along with the IU DCC will be included. The writing group will include a limited number of investigators from clinical centers and Data Coordinating Center (DCC).
* Secondary or lesser reports of main clinical studies will have modified conventional authorship (Name1, name2, ..., for the for the AlcHepNet Clinical Centers) or conventional authorship. An appendix listing all investigators of the AlcHepNet Clinical U01 along with the IU DCC will be included if the paper has modified conventional authorship, journal permitting
* Authorship format for ancillary study reports should be proposed by the ancillary studies writing group and will be subject to review by the Presentations and Publications Committee. Ancillary study abstracts and manuscripts will have either conventional authorship (Name 1,

Name 2, …) or modified conventional authorship (Name1, Name2, for the AlcHepNet Clinical Centers). Regardless of the authorship format, the AlcHepNet must be identified as the source of the biosamples used in the ancillary study. Modified conventional format requires that the data analysis must be either done by the DCC or confirmed by the DCC. The authorship format must be specified on the Ancillary Study proposal form and, at the time of the initial manuscript review by the Presentations and Publications Committee, must be confirmed by both the Presentations and Publications Committee (majority vote).

***If conventional authorship***: 1.) the NIAAA AlcHepNet must be acknowledged as the source of the biosamples, taking care not to state or imply that the NIAAA approved the contents of the manuscript; the institution’s grant number should be included 2.) AlcHepNet investigative group members may be listed as authors only if they participated in the writing of the manuscript; 3.) the SC member who served as the ancillary study liaison will participate in drafting and review of the manuscript and will be a named author; 4.) the AlcHepNet DCC must not be acknowledged in the paper, although individual DCC members may be listed; 5.) copies of both the submitted and accepted versions of the paper must be provided to the Presentations and Publications Committee on an informational basis

***If modified conventional authorship***: 1.) the NIAAA AlcHepNet must be acknowledged as the source of the biosamples; 2.) the AlcHepNet investigative group members may be listed as authors only if they satisfy the authorship requirements in the statement by the ICMJE guidelines; 3.) the paper must contain a section, an appendix, or an online supplement crediting the AlcHepNet Clinical Center investigators (with grant numbers) who provided the biosamples or other materials or services used in the ancillary study; 4.) the SC member who served as the ancillary study liaison will participate in drafting and review of the manuscript and will be a named author; 5.) the AlcHepNet DCC must be acknowledged for provision of the biosamples, their role in the analysis, and, if appropriate, DCC staff may be listed as authors

# Proposal of topics and review of proposed topics

* The DCC will maintain a continuously updated list of proposed and approved manuscripts and their status. This list is available on the password protected AlcHepNet proposals web page
* Only Clinical Center investigators may propose presentations and publications stemming directly from the Clinical Studies. Other investigators of the AlcHepNet may propose a manuscript but they need to channel their requests through one of the Clinical Center PIs. But, in general, publications directly resulting from the clinical studies are primarily meant for the clinical center investigators.
* Proposals must be submitted in writing to the P&P Committee by completion of the Abstract/Publication Proposal (PP) form which is available on the AlcHepNet website. This form requires: A brief description of the background, hypothesis, and purpose of the topic and a summary of the analysis plans

A description of the subjects to be included

A list of variables of interest

Proposed writing group membership (including statistician) and proposed chair For abstracts, the date of submission and date of the meeting

For manuscripts, target journals or book

Sign-off by proposing investigator that he/she has reviewed the existing AlcHepNet proposals and that the proposal does not significantly overlap with any existing proposals

* Prior to submitting a publication proposal for P&P Committee review, all authors listed on the proposal must review and give their approval
* Publications arising from ancillary studies will generally not require a publication proposal if the aims of the manuscript align with the aims in the Ancillary Study proposal, but will be assigned a manuscript number for tracking purposes. The manuscript number will be assigned when an abstract or manuscript is submitted for review
* Criteria for judging proposals:

1. Scientific merit of the hypothesis or aim of the proposal
2. Availability of appropriate data to address the hypothesis or aim

* If overlap in content exists between or among proposals, the P&P Committee will either eliminate overlap or consolidate the proposals

# Responsibilities of the writing group

* The chair of the writing group will be responsible for assigning tasks to other members of the writing group and for overseeing the completion of these tasks on schedule
* Manuscripts will be prepared at the center of the writing group chair
* All data analysis will be done through the DCC (mainline papers) or appropriate statistician at a AlcHepNet site
* Prior to submitting a manuscript for internal review by the P&P Committee, all authors must review and give their approval
* When the manuscript is judged ready for internal review, the chair will submit the completed manuscript to the DCC for distribution to the P&P Committee members
* If a writing group does not complete its work or fails to meet timeline milestones, the P&P Committee may reassign the roles of chair or select new writing group members. This exigency may be exercised if no draft is produced within 6 months of the availability of a clean data set
* If, during the course of work on a manuscript, the analysis is found to be too broad for a single manuscript, the writing group may suggest to the P&P Committee that the data would be more suitable for more than a single manuscript. The writing group must notify the P&P Committee that they plan to narrow the scope of the manuscript
* Writing group members may withdraw or be withdrawn from the writing group if their participation is insufficient to warrant co-authorship

# Acknowledgments to be included in publications and presentations

* All AlcHepNet manuscripts must include an acknowledgment of NIAAA funding, with specific grant numbers. An AlcHepNet support statement can be found on the AlcHepNet website.
* Ancillary study manuscripts should acknowledge the AlcHepNet as the source of biosamples and include the grant number(s) for the clinical center(s) associated with the ancillary study

# Review of manuscripts

* The P&P Committee will serve as the editorial review committee for all manuscripts
* Manuscripts that are judged ready for P&P review should be submitted to the DCC for distribution to the P&P Committee members
* Two primary reviewers with relevant expertise (mostly from within the AlcHepNet) will be identified by the P&P Committee and DCC to provide a timely review (within two weeks) of the manuscript for editorial clarity and data integrity. Ancillary study reports with modified conventional authorship are assigned one primary reviewer. Occasionally, reviewers from

outside the AlcHepNet may be selected if they have particular expertise related to the manuscript (GWAS, radiology, or microbiome, for example).

* The DCC will simultaneously do their own review of the analysis and statements about the AlcHepNet.
* The results of the assigned and DCC reviews will be collated by the DCC and sent to the writing group chair and coauthors for preparation of a revised manuscript. The writing group chair may discuss the planned response of the writing committee to the comments with the P&P Committee chair or full committee by conference call if needed
* If requested by the P&P Committee, a revised manuscript will be reviewed for appropriate responsiveness to the comments. If the response is acceptable, the revised manuscript will be approved for journal submission
* If a dispute occurs between the authors and the P&P Committee, resolution of the dispute is the responsibility of the Steering Committee
* Review of manuscripts involving third-party (industry) collaborations will occur per the terms of the agreement. Third-party (industry) collaborations occur through two general mechanisms - either through an agreement between a network site and the collaborator, or through a CRADA/CTA between NIAAA and the collaborator. The agreements between collaborators and institutions are subject to review by NIAAA while CRADA/CTAs are negotiated by NIAAA. In both situations, the terms of the agreement with the collaborator will dictate the requirement and timing of review of manuscripts by collaborators. There may be a provision in the applicable agreement that allows for a brief delay (defined in the specific agreement) in publication in situations where the third-party collaborator requires additional time to protect their patent position. Third-party collaborators will not have the authority to prevent publication.
* Ancillary study reports with modified conventional authorship will be sent to one AlcHepNet member with relevant expertise for review for accuracy of statements about the AlcHepNet resources used in the ancillary study and for appropriate acknowledgment of the AlcHepNet. Those with conventional authorship are not reviewed, but should be submitted to the P&P Committee on an informational basis.

# Publication priorities

* No investigator may jeopardize the publication of AlcHepNet study results in a peer-reviewed journal by releasing or presenting data prematurely. Local press releases are to be timed to coincide with publication of manuscripts and must respect any applicable publication embargoes
* No individual site will be permitted to publish site-specific AlcHepNet results without the approval of the Steering Committee

# Presentations, abstracts, and letters to the editor

* Investigator-initiated abstracts that require data analysis assistance from the DCC must be proposed to the P&P Committee at least 3 months prior to the internal review submission deadline (use the same form used to propose a manuscript). The P&P Committee will review the proposal, and if approved will prioritize the analysis requests, in consultation with the DCC
* Completed abstracts are to be submitted to the P&P Committee at least 2 weeks prior to submission to the organization sponsoring the meeting. All authors must review and approve of the abstract prior to submission to the P&P Committee. Abstracts must include the authorship line and institutional affiliation. The abstract will be circulated to the full P&P Committee with a ballot for approval as written, approval with revisions, disapproval, or tabled for further discussion by the Steering Committee. A majority of the P&P Committee members responding must approve the abstract for it to be approved for submission. Abstracts submitted fewer than 2 weeks prior to the due date will be reviewed in time for submission if possible, but the P&P Committee cannot guarantee completing the review in time to meet the due date
* Presentations and abstracts will generally use modified conventional authorship (name 1, name 2, ..., etc., for the AlcHepNet Clinical Centers) or conventional authorship and will include acknowledgment of NIAAA funding
* Letters to the editor are to be approved according to the same process as that used for abstracts

# Postings to the AlcHepNet website

• Final versions of AlcHepNet manuscripts will be posted on the AlcHepNet website. Slide material prepared for presentation at national or international meetings will also be posted on the AlcHepNet website

**Acknowledgments:**

In drafting the AlcHepNet Presentations and Publications Policy and Procedures, we primarily depended on the NASH CRN P&P Policy and Procedures. The NASH CRN referred to the following sources in preparing its document: Publication and Presentation guidelines of the Virahep-C and HALT-C studies sponsored by the NIDDK, and the Presentation and Publication Policy and Procedures of the National Emphysema Treatment Trial sponsored by the NHLBI.