A. Introduction

This document provides the policy for publications and presentations of the NIDA National Drug Abuse Treatment Clinical Trials Network (CTN). The Publications Subcommittee will implement the policy to promote publications and ensure the scientific quality and timeliness of CTN publications. The Publications Subcommittee serves as an advisory committee to the Steering Committee, which has final authority for approval or disapproval of recommendations of the Publications Subcommittee.

B. Publications and Presentations Definition

1. Data-based articles, methodological papers, monographs, book chapters and other CTN related material to be published in scientific journals and other scholarly literature
2. Presentations at scientific meetings (oral and posters).
3. Publications of CTN materials (e.g. books, monographs, training manuals, therapist manuals, summaries of study protocol and trial progress reports).
4. Other products of the CTN including methodology and other know-how or information regardless of form (e.g. research instruments, computer software, video and audio taped materials) that are produced from CTN activities
5. Exception:
   a) Materials (e.g. posters, handouts, recruitment cards) or presentations used solely to promote enrollment or inform professional audiences of the CTN structure, purpose, or clinical trial design. Such materials should not include discussion of previously unpublished data and must not result in publication of study results.
   b) Press releases: NIDA will provide the Steering Committee with its current policy and the Steering Committee will write a procedure for press releases that is independent of the Publications policy and/or procedures. However, any press release related to publications and the Publications Subcommittee would process presentations.

C. Purpose of Publications Subcommittee

1. To facilitate and ensure timely submission and dissemination of high quality publications and presentations based upon data from the CTN studies to the drug treatment and scientific communities.
2. To review proposals for presentations and publications.
3. To review content of presentations and publications to determine their scientific merit and readiness for submission.
4. To review authorship of manuscripts and to determine and ensure equitable participation and attribution.
5. To offer recommendations and establish guidelines concerning appropriate and equitable recognition of the contributions of all participants.
6. To prevent publications that
   - are factually or conceptually inaccurate.

- may inappropriately impair the CTN function, including enrollment.
- prematurely release data that might subsequently preclude publication of results in high quality peer reviewed journals.

7. To coordinate and prioritize the order of the multiple publications that will emanate from the network.
8. To safeguard the confidentially of volunteer participants.
9. To implement the publication policies described in the "Terms and Conditions of Award", and this document.

D. Publications Subcommittee Responsibilities

1. Prepare detailed publications and authorship procedures.
2. Plan and solicit publication proposals.
3. Review of proposals to initiate an analysis project presentation or other scientific communication
4. Review of manuscripts and abstracts prior to submission
5. Report regularly on the status of all proposed and ongoing trial publications to the Steering Committee.
6. Keep accurate minutes of all meetings and distribute copies to relevant parties.
7. The Publications Subcommittee will propose changes in publications policy and procedures as needed as the trial evolves

E. General Principles

1. All presentations and publications based upon data collected, as part of the CTN shall be submitted to the Publications Subcommittee for review and approval recommendation.
2. The participants shall be encouraged to submit topics for publications and presentations. The Subcommittee will review the topics and will determine the suitability, overlap with other projects, and the priority for preparation.
3. After approval of a publication or presentation topic, the Publication Subcommittee will notify the submitting individual who in turn will select the Writing Committee and will send to the Steering Committee for final approval. The Writing Committee should reflect trial participation, preserving the writing/authorship roles of primary study leaders if they so desire.
4. Before submission to journals, the Publications Subcommittee will review and submit a written evaluation and recommend approval, approval with modifications or disapproval to the Steering Committee.
5. Studies where a group that is not formally part of the CTN analyzes CTN data should follow the same procedures unless another procedure is mutually agreed upon and codified in a letter of agreement.
6. In the case of pharmaceutical collaborators, the Clinical Trials Agreement between NIDA, and the pharmaceutical collaborator(s) should specify that these guidelines would be followed. Alternative procedures may be followed if all parties (including the Steering

Committee) mutually agree upon modifications to these guidelines and codified in the Agreement.

7. In the case of collaborative studies with co-sponsoring agencies or other clinical trials groups, the letter of agreement must reflect that the guidelines of the CTN Network group will be followed.
8. Proper acknowledgment of the funding agency is also required in all publications and presentations.
9. Any decisions of the Publications Subcommittee can be appealed to the Steering Committee.

F. Publications By Those Outside The CTN

If a researcher from an institution that is not a participating center proposes to participate in analysis of and produce a publication from CTN data, she/he will submit a request in writing to the Publications Subcommittee describing the project proposed. The Publications Subcommittee will consult the Steering Committee and decide whether, and on what conditions the information can be released for that purpose.

Publication or presentation projects related to trial data may also be proposed by investigators who are not members of the Steering Committee, but who are part of institutions participating in CTN. Such projects are proposed through the same Publications Subcommittee channels described above. In such cases, at least one member of the Steering Committee would normally participate in the collaborating research team.