I. Policy Objectives

The objectives of this editorial policy for publications, abstracts, and presentations are:

A. To assure and expedite orderly and timely presentation of LONGSCAN results and data to the scientific community.

B. To have accurate and scientifically sound abstracts, presentations, and papers from LONGSCAN and its collaborating investigators.

C. To assure that all investigators, collaborators, and other related professionals have the opportunity to participate and be recognized in consortium-wide presentations and the preparation of cross-site LONGSCAN papers.

D. To assure that abstracts, press releases, interviews, presentations, and publications are accurate and objective, and do not compromise the collaborative project and the acceptance of its results.

E. To state clearly that all designated LONGSCAN authors are responsible for the contents of consortium abstracts, presentations and papers.

F. To protect the acronym LONGSCAN from misapplication/misuse and to assure that each abstract, presentation, publication, interview, or press release that cites LONGSCAN results using cross-site data (defined below) has been reviewed and sanctioned by the Publications Committee of the Consortium. Furthermore, the Publications Committee shall be notified of each abstract, presentation, publication, interview, or press release that presents or discusses LONGSCAN data or results from any single site of the Consortium.

II. Definitions

A. "Common data" are any data collected at sites as part of the LONGSCAN protocols and/or entered into the LONGSCAN data entry system.

B. "Cross-site Data" refers to common data derived from more than one site.

C. "Site-specific data" refers to data gathered at any individual site that is not part of the common LONGSCAN protocols.

D. "Principal Investigator" (PI) means the single investigator from the coordinating center or any site designated in a grant, subcontract, or other agreement with ultimate responsibility for the direction of either the
coordinating center or a site. Two or more persons may share the title “Co-principal investigators” for a specific cohort study if their university or granting agency permits, but sections of this policy which specify a voting right for the PI allows only one vote per site (Site co-principal investigators may collaborate in casting the one allotted site vote, or decide between them who will cast the one allotted site vote).

E. “Affiliated Investigator” means any member of the coordinating center staff or any individual site staff involved in the conduct of either the participating cohort study or the shared design and analysis.

F. “Publications Committee” This committee consists of the PIs at each site and the coordinating center or their designated representatives. Investigators from the Collaborative Studies Coordinating Center (the contractual organization that maintains the LONGSCAN database; also referred to as the Biostatistics Unit at the Coordinating Center) also serve as non-voting members of this committee. (NOTE: The membership of this committee is identical to the membership of the Executive Board of the Consortium.)

This committee will:
1. be responsible for recommending or modifying policies regarding both data analysis of the cross-site data and publications
2. establish authorship guidelines
3. receive, and evaluate for approval and use of the LONGSCAN imprimatur, proposals for cross-site data analyses, presentations and papers
4. prioritize analyses and coordinate the analysis of research questions between and among the collaborating investigators
5. arbitrate disagreements over authorship, research questions, or related areas involving scientific research
6. receive any questions regarding analysis of cross-site data from investigators not otherwise associated with LONGSCAN

G. “Data Handling and Analysis Committee” This committee will be composed of the lead statisticians from the coordinating center and either the PIs or affiliated investigators with statistical expertise at each of the individual study sites.

This committee will:
1. when requested, make recommendations regarding the appropriateness of statistical analyses.
2. make recommendations regarding data management and derived variables.
3. investigate issues such as attrition, site differences, and aspects of longitudinal analysis.
III. Publications Protocol

A. For proposals using cross-site data:

1. The Biostatistics Unit of the Coordinating Center will distribute the cross-site data two times per year; but the data will be retrieved four times during the year. If needed by an investigator, the newly retrieved dataset can be requested up to four times per year. (This statement was approved on 07/21/03.)

2. No public presentation of results of any cross-sectional or longitudinal data analysis of cross-site data will be undertaken until 90% of the data for a given time point has been collected and processed at the Biostatistics Unit of the Coordinating Center. Under special circumstances, for specific manuscript proposals, the Publications Committee can be petitioned (by the lead collaborator for a manuscript) to consider suspending the 90% Rule in order to promote timely dissemination of LONGSCAN data.

3. When the data are 90% complete and the Biostatistics Unit of the Coordinating Center indicates that the data are retrieved, all LONGSCAN investigators are eligible to submit a brief Manuscript Proposal Form (MPF).

The following was initially stated as policy at the Executive Committee Meeting on March 19, 2004 and was later clarified and approved for enforcement on a PI Conference Call on April 1, 2005:

"In the interest of efficiency and productivity – primary authors lead only one cross-site paper at a time"

This means that primary authors are to have only one ‘in progress’ cross-site manuscript at a time. ‘In progress’ is defined as the time between submission of an MPF and submission of the manuscript to a journal.

4. The Publications Committee will review and approve the proposed analyses, and will recommend additional investigators interested in working on the analysis. Working groups of investigators who have been approved to work on specific analyses will then develop presentations and papers. All data analyses, abstracts, or reports involving cross-site data must be approved by the Publications Committee prior to submission for presentation or publication. Members of the committee will have seven days from the time of notification to object to a proposed presentation or publication before a non-response will be considered as an approval.

5. When requested, the Biostatistics Unit of the Coordinating Center is available to review any proposed or completed analyses of cross-site or site-specific data.

6. The organizer of each presentation/publication citing cross-site data bears the
responsibility of ensuring that all steps outlined in this Policy do indeed occur in the writing process for a cross-site presentation/publication. (This statement was approved and added to this Policy in April 2003.)

B. For local site proposals using site-specific or common data:

1. It is assumed that each LONGSCAN site and principal investigator will publish analyses of site-specific data. However, it is in the best interests of LONGSCAN to be recognized for our collaborative efforts. Therefore, site investigators are encouraged to acknowledge LONGSCAN.

2. The Publications Committee shall be notified of all abstracts, reports and publications using site-specific or common data, but review and approval are not required.

IV. Manuscript Proposal Development

A. The LONGSCAN Manuscript Proposal Form can be found as an addendum to this document.

B. Manuscript generation using cross-site data can begin with any LONGSCAN investigator. The idea for the manuscript should be discussed with the local site PI before initiating discussion among all LONGSCAN PIs. These discussions are followed by the preparation of a Manuscript Proposal Form, which is to be submitted to the LONGSCAN Study Coordinator at the Coordinating Center for distribution to the LONGSCAN Publications Committee. The Publications Committee will review, discuss, and approve the proposal, or return it to the lead organizer of the proposal for further development. The Publications Committee will serve as the final arbitrator for all conflicts. Before a manuscript proposal can be considered final, the author of the proposal should invite to participate in the writing group, all interested representatives from throughout the LONGSCAN Consortium.

C. Following study-wide discussion, the flow of cross-site LONGSCAN Manuscript Proposals proceeds as follows:

1. Proposal prepared and submitted to the Study Coordinator at CC.
2. Publications Committee Review/Approval.
3. Identification/signing on of Writing Group Members from each site.
4. Dataset requests/Analysis. If preparation of the manuscript requires a customized dataset, the lead organizer collaborates with Biostatitistics Unit Staff to write a Statistical Computing Request (SCR) to request the dataset needed.
5. Writing group preparation of draft manuscript. Pursuant to the PI decision made on 03/14/05: Work progress will be checked monthly.
6. Submission of draft manuscript with proposed authorship order to Publications Committee for approval.
7. Analysis/data review by the Biostatistics Unit of the Coordinating Center if requested by the organizer of the manuscript.
8. Publications Committee clearance of final manuscript.
9. Submission to journal.

V. Authorship of Publications Citing Cross-site Data

General Statement (Excerpt from Guidelines for Research at the University of North Carolina at Chapel Hill): A gradual diffusion of responsibility for multi-authored or collaborative studies has led in recent years to the publication of papers for which no single author is prepared to take full responsibility. Two critical safeguards in the publication of accurate scientific reports are the active participation of each co-author in verifying that part of the manuscript that falls within his/her specialty area and the designation of one author who is responsible for the validity of the entire manuscript.

A. It is understood that each investigator of the LONGSCAN Consortium has a commitment to collaboration across sites in the writing process for each publication or presentation that reports cross-site data.

B. A contribution to the writing of a paper is required to be an author. Authorship is earned by making a substantial intellectual contribution to a piece of research.

C. Every site has the right to be offered the opportunity to participate in authorship on LONGSCAN papers if cross-site data are used. However, a contribution to the writing of the paper is necessary for authorship.

D. It is assumed that investigators from every site will have the opportunity to serve as primary author for a publication. Authorship positions 2 through 7 will include a representative from each site. The primary author will recommend position (order) among other authors based upon contribution. If desired, the primary author may petition the Publications Committee to recognize an alternate order of authorship. Any site has the right to “pass” on authorship of any paper in which the site does not have sufficient interest to participate in the writing process.

E. To be listed as a co-author on a published LONGSCAN work, each co-author must, as a minimum requirement read, critique, and reply to the drafts provided by the lead author. If the co-author sees nothing in need of changing or adding s/he must reply to this effect to the lead author as evidence of having reviewed the document critically. Failure to meet the minimum standard can result in being dropped as a writing group member. If a writing group leader thinks a writing group member should be dropped, s/he should bring this to the attention of the Publications Committee for its determination of action. In addition to these specific minimum requirements of co-authors, it is expected that co-authors will be actively involved in the significant tasks of
conceptualizing the manuscript, identifying the appropriate approach to analyzing the data, and interpretation of the results.

F. Co-authorship is not typically given for collecting data, statistical programming, reviewing just one draft, having discussions regarding the manuscript, or serving as the PI with no other involvement.

G. All writing group leaders are required to circulate drafts of the manuscripts for member review and revision. Each co-author should be given a copy of the manuscript when it is ready for submission to a journal; and must review and approve it before it is submitted for publication.

H. It is emphasized that accepting lead or co-authorship of a paper implies a responsibility as well as a privilege. Each author listed on a publication should be prepared to defend its contents publicly. If a potential co-author has reservations about a publication, s/he should decline co-authorship.

I. The lead author should never include the name of a co-author without that person's consent.

J. Because authorship on publications is understandably limited, boilerplate acknowledgement lists recognizing the contribution made by additional LONGSCAN staff will appear on LONGSCAN publications when appropriate.