



**POLICIES AND PROCEDURES
FOR THE COMMUNICATION
OF SCIENTIFIC RESULTS
FROM THE
CATIE RESEARCH PROGRAM**

December 2, 2003

I. INTRODUCTION

The CATIE research program is a clinical trials and services research organization established and funded by the NIMH, and based at the University of North Carolina, in affiliation with other academic healthcare institutions (including Duke University, University of Southern California, University of Rochester, and Yale University) and Quintiles. The primary purpose of this program is to conduct studies to evaluate the comparative effectiveness of available treatments for disorders in which antipsychotic medications are indicated.

The CATIE policies and procedures for the communication of scientific results were developed to ensure an efficient, accurate and scientifically coherent communication plan for the results of the CATIE trials. These policies and procedures are intended to ensure that the data generated by CATIE are reported in an accurate, consistent, and timely manner, and to ensure that the CATIE Executive Committee and Data Analysis and Technical Assistance Center (DATAC) exercise final review responsibility over all presentations and publications of CATIE data. These policies and procedures were developed with reference to those policies of similar large multi-center studies funded by the NIH and to be consistent with the standards described in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals of the International Committee of Medical Journal Editors. These policies and procedures govern all analyses, presentations and publications involving data collected in the context of the parent CATIE trials. These policies and procedures also apply to ancillary studies that use the CATIE database. The policies and procedures for the communication of the scientific results from the CATIE research program have been developed, reviewed and approved by the CATIE Executive Committee, and reviewed by the CATIE Publications Committee and Data Analysis and Technical Assistance Center and by the NIMH project officers.

The CATIE Publications Committee consists of members of the Executive Committee and representatives of the Schizophrenia and Alzheimer's Disease trial centers and site PIs from each of the trials. The role of the Publications Committee is to review and approve these Policies and Procedures for the Communication of Scientific Results from the CATIE Research Program. After the initial approval of the policies and procedures, the Publications Committee will be convened twice a year to evaluate the policies and procedures and make changes as needed.

Specifically, the guidelines contained in these policies and procedures are intended to:

- Ensure quality control for all data analyses and scientific communications from the CATIE research program.
- Ensure that the data from the CATIE research program are reported to the scientific community in an accurate, consistent, and timely manner.
- Ensure that the results of CATIE are efficiently communicated to the academic and broader mental health care community, in order to advance health care and treatment.
- Offer opportunities to CATIE researchers to participate in the analysis and reporting of data from the CATIE trials.
- Delineate the mechanisms for establishing *ad hoc* writing groups, accessing data and data analyses, and for obtaining review and approval for presentation and/or publication of CATIE data.
- Establish and maintain a complete archive of CATIE-related presentations and publications.

II. DEFINITIONS

Primary analyses, presentations and publications are those reporting results that reflect data collected at all sites and that directly address the **specific aims** of the CATIE Alzheimer's disease or Schizophrenia trials.

Secondary analyses, presentations and publications are those covering secondary, exploratory, and *post hoc* analyses and other aspects of the project involving CATIE data gathered from the trial sites. Examples of topical areas include, but are not limited to: health services and cost effectiveness, comorbid disorders, adjunctive or concomitant medications, competency to consent, treatment adherence, properties and performance of assessment instruments, etc.

Tertiary presentations and publications are those reporting work done in a subset of the patient samples of the trials, performed at one or more sites. Manuscripts reporting local findings may only be submitted after the papers reporting primary or secondary analyses covering the same topical areas have been published or accepted for publication, or if the Executive Committee does not anticipate publication of primary papers covering the same topic.

III. GENERAL PRINCIPLES

The determination of authorship for presentations and publications will be based on standards of scientific scholarship and academic equity.

All CATIE investigators and site PIs will be acknowledged in the CATIE Research Group identification on all presentations and publications.

Being a CATIE investigator or researcher, alone, is not an adequate criterion for authorship.

Lead and co-authorships will be determined based on the principles and criteria described below and will reflect the roles of candidate authors in the conception, formation and implementation of the project, as well as roles in data analyses and writing of the manuscript.

If the number of co-authors is limited by journal conventions, authors beyond the limit will be recognized by the CATIE Research Group identification. The following criteria will be utilized in a system for allocation of authorship.

1. Role in the study's development
2. Role and effectiveness in the overall study's implementation
3. Role and effectiveness in study implementation at individual site(s)
4. Source of idea for analysis or report.
5. Role in data analyses.
6. Role in writing the article.

Eligibility and Prioritization of Authorship

The following individuals comprise the group of potential authors for scientific communications from the CATIE Project.

- CATIE Executive Committee
 - DATAC Investigators
 - Site PIs
 - CATIE Consultants, Trial Center Advisors, and Committee members
 - Ancillary Study PIs and designated co-investigators
 - NIMH Program Officers
1. The CATIE Executive Committee members (Lieberman, C.E. Davis, McEvoy, Schneider, Stroup, Tariot, Keefe, Perkins, Rosenheck, Swartz) have priority for authorship on all communications from data generated by the CATIE Trials. They will participate in the conceptualization and preparation of all primary and secondary presentations and publications emanating from the CATIE Trials to the extent that they are able and is reasonable. They will be listed as lead or co-authors on all communications for which they have provided significant input.
 2. The DATAC investigators (S. Davis, Koch, and associate biostatisticians) will participate in the conceptualization and preparation of all primary and secondary presentations and publications of the CATIE trials and will be listed as co-authors on all communications for which they have provided significant input.
 3. Lead and co-authorship on secondary presentations or publications are available to individuals who participate in an *ad hoc* writing group (*vide infra*) approved by the Executive Committee and who effectively direct data analysis and manuscript development through to journal submission.
 4. CATIE co-investigators and site PIs may propose ideas for other analyses and scientific communications.
 5. Authorship considerations that cannot be resolved within the writing groups will be decided by the Executive Committee.
 6. All primary, secondary, and tertiary manuscripts must be submitted to the Executive Committee for review prior to submission externally.
 7. The Executive Committee will have final review responsibility over publications reporting procedures and/or results from the CATIE trials.

To resolve any differences or questions regarding authorship or prioritization of data analyses the following criteria will be used:

1. Scientific merit
2. Resource requirements
3. Number of prior proposals and requests of the investigator serving as lead author of the analysis and report.
4. Overall contribution to the study.

IV. DATA ACCESS AND TECHNICAL ASSISTANCE CENTER (DATAC)

The CATIE Research Program has established a DATAC that will be able to conduct analyses beyond those specified in the formal data analysis plans of the ongoing CATIE trials. The purpose of the DATAC is to conduct analyses that will maximize the scientific yield of the study and that will advance the understanding and treatment of persons with severe mental illnesses.

The CATIE Executive Committee has established procedures for accessing data and/or requesting analyses. The Executive Committee will review each request and decide on its appropriateness and feasibility within the guidelines and pragmatics of the program. This review will ensure that requests do not conflict with other proposed or ongoing analyses and provide for a consistent and coherent publication strategy. Analyses will be conducted by the CATIE DATAC in conjunction with the client investigator. All presentations or manuscripts that describe the CATIE studies or its data must be developed in accordance with the Policies and Procedures for the Communication of Scientific Results from the CATIE Research Program.

V. INITIATION OF A MANUSCRIPT PROPOSAL FOR A JOURNAL PUBLICATION

The procedure for proposing analysis and scientific communication by a CATIE affiliated investigator follows. The investigator who wishes to be lead or co-author proposes a manuscript topic to the CATIE Executive Committee. This topic is then reviewed and evaluated by the criteria described above. If the topic is approved, then an *ad hoc* writing group will be determined from the relevant Working Group and the potential group of co-authors. The *ad hoc* writing group completes a Manuscript/Presentation Proposal Form (MPPF attached), and submits the MPPF (which will list the membership of the writing group) to the CATIE project office for initial review by the Executive Committee. If approved, then the proposal will be assigned a priority and distributed to the DATAC.

The Executive Committee may also recommend specific topics for primary, secondary, and tertiary manuscripts.

Access to CATIE data by non-CATIE investigators during the period of exclusivity. Investigators wishing to analyze CATIE data should submit a one-page summary of their proposal to the Executive Committee. The Executive Committee will determine if the proposal conflicts with plans or interests of CATIE investigators. In many cases this will involve contacting the leader of a Working Group to determine the plans and interests of the Working Group's membership. If no CATIE investigator has conflicting plans for the data, the non-CATIE investigator will then be advised to prepare an application to the Ancillary Studies Committee.

VI. MANUSCRIPT DEVELOPMENT

The designated *ad hoc* writing group is responsible for writing the manuscript within agreed upon guidelines, format, and time limit.

The lead author is responsible for developing a detailed manuscript outline, distributing writing assignments and timetables to the co-authors, and interacting with the DATAC to obtain the necessary data and analyses.

In collaboration with the *ad hoc* writing group, the DATAC develops and refines an analytic plan, and implements the appropriate analyses. The analyses are checked for accuracy according to standard DATAC procedures, and sent to the lead author who distributes them to the co-authors. Further data analyses are requested and performed until all analyses required for production of the manuscript are complete.

Drafts are circulated for review by the lead author and are re-written as needed. The lead author seeks formal approval of a finished draft of the manuscript from all the co-authors, and proposes an order of authorship that reflects individual contributions to the manuscript's development.

The Executive Committee will monitor the progress of the writing groups and review the completed drafts offering suggestions and revisions as appropriate. The Executive Committee may make changes to the writing group based on lack of progress and changing circumstances.

A time limit within which lead authorship assignments must be initiated and/or completed will be established (e.g. six months from assignment and availability of data to the production of a first draft of manuscript). After this time has elapsed lead authorship may be reassigned.

VII. INTERNAL REVIEW, SUBMISSION, AND ARCHIVING OF MANUSCRIPTS

The lead author sends the finished draft of the manuscript to the Executive Committee and DATAC with a cover letter stating that all proposed authors have contributed to, reviewed, and approved the draft. The letter also proposes an author line and a journal to which the manuscript will be submitted.

The manuscript will be reviewed by the Executive Committee and DATAC. The Executive Committee may then: (a) approve of the manuscript as is, (b) approve of the manuscript with recommended changes, or (c) recommend revision and re-submission. Resubmissions will be sent back to the Executive Committee for re-review, and permission to submit for publication. Every effort will be made to review these submissions within 30 days.

The NIMH Government Project Officer (GPO) will participate in the pre-publication review of all manuscripts based on data funded by the CATIE contract.

The lead author submits the manuscript to a journal agreed to by the Executive Committee and keeps the committee informed of its status.. If a manuscript is rejected, the lead author consults with the Executive Committee regarding the reviews and possible selection of another journal for submission of the manuscript.

The lead author supplies the co-authors, the Executive Committee, and the DATAC with copies of the galleys and publication.

VIII. SLIDE/POSTER PRESENTATION PROCEDURES

The lead author proposes a presentation topic, identifies co-authors, and enlists their collaboration in an *ad hoc* writing group, submits a Manuscript/Presentation Proposal Form (MPPF attached), to the Executive Committee. If approved, then it is assigned a priority and distributed it to DATAC.

Overlapping presentation and manuscript proposals should be submitted simultaneously to avoid duplication of effort.

MPPFs submitted for approval must be received NO LATER THAN 14 DAYS before submission deadlines for the meeting where the abstract is to be presented, if all required data analyses have already been completed for the preparation of a manuscript addressing the same topic. MPPFs requiring new data analyses will enter the sequence set by the Executive Committee and DATAAC, and earlier submission will be associated with greater likelihood of completion in time to meet deadlines.

The NIMH Government Project Officer (GPO) will participate in the pre-presentation review of all slide or poster presentations based on data funded by the CATIE contract. The selection of individuals to do presentations will follow the principles delineated above for the selection of manuscript authorship.