NATIONAL DRUG ABUSE TREATMENT CLINICAL TRIALS NETWORK (CTN) BYLAWS
(Effective March 2003)

ARTICLE I - Name

The Name of this organization is the National Drug Abuse Treatment Clinical Trials Network (CTN).

ARTICLE II - Objectives and Purposes

A. Conduct studies of behavioral, pharmacological and integrated behavioral and pharmacological treatment interventions in rigorous, multi-site clinical trials to determine effectiveness across a broad range of community based treatment settings and diversified patient populations

B. Timely transfer of the research results to clinicians, providers, their patients and the policy makers to improve the quality of drug abuse treatment throughout the country using science as the vehicle

ARTICLE III - Organization

The CTN operates under cooperative agreements between academic research institutions and the National Institute on Drug Abuse (NIDA) and is administered by the Center for Clinical Trials Network (CCTN) of NIDA.

Network Structure

Clinical Trials Network (CTN). A collaborative group of geographically diversified Regional Research Nodes working collaboratively with NIDA to conduct multi-site and cross-regional (nationwide) clinical trials on promising behavioral, pharmacological or integrated treatments.

NIDA CCTN Office. An office within NIDA, responsible for the scientific, administrative, budgetary and operational management of the CTN.

NODE. A Node is the functional unit within the CTN consisting of the Regional Research and Training Center (RRTC) and its affiliated Community Treatment Programs (CTPs). The RRTC serves as the coordinating core and promotes a bi-directional research partnership between the RRTC and CTPs.

Regional Research and Training Center (RRTC). The RRTC is the recipient of the cooperative agreement award. It is one of the two components of a Node. It resides in the Principal Investigator's research and prevention institute or organization's academic medical center. The

principal investigators at these sites are recognized nationally and internationally as scientific experts in substance addiction treatment. The RRTC provides a core of administrative and study operations services as well as scientific leadership and management of clinical trials.

Community Treatment Programs (CTPs). Drug abuse treatment programs in a community (typically non-university-based) setting that have a history of providing quality treatment to large and diverse patient populations, and have the capability for and interest in participating in controlled clinical trials.

CTN Steering Committee. The Steering Committee (SC) constitutes the primary governing body of the Network. The members of the SC review and approve the research agenda, formulate and monitor policies and procedures guiding the research activities, oversee communications within the CTN as well as with the greater scientific community and the public.

NIDA's CTN Protocol Review Board. An expert board appointed by and reporting to the NIDA CCTN Director to review the protocol and informed consent submitted by the CTN for scientific and regulatory review.

Data and Safety Monitoring Board (DSMB). The DSMB is an expert board appointed by and reporting to the NIDA CCTN Director. This Board will (1) review protocols for scientific integrity and safety prior to study implementation and (2) provide oversight monitoring of ongoing trials; assuring safety of participants and trial integrity (including data integrity). The DSMB will make recommendations to NIDA CCTN with regards to trial continuation or early termination.

CTN Ad-hoc Oversight Board. An expert board appointed by and reporting to the Director of NIDA. It oversees all activities conducted by the CTN. The Board will advise the NIDA Director regarding the programmatic advisability of proceeding with studies proposed by the CTN Steering Committee and will assist NIDA in prioritizing and approving research concepts. Research concepts will not be implemented without the approval of NIDA Director.

Central Data Management Center (CDMC). Data information systems operated by each Node are required to implement standards established by the CTN. Such standards guide the development of protocol-specific electronic case report form (e.g. CRF) applications each Node is responsible for implementing at participating CTP sites. The Central Data Management Center (CDMC) reports directly to the Director, CCTN, although functions as a resource to the CTN in all matters related to data management.

Administrative and Logistical Support. Contract(s) awarded by NIDA to provide centralized support for the administrative and logistical functions of the CTN.

ARTICLE IV - Membership

SECTION A. Voting Members of the CTN:

1. The voting members of the CTN shall be the Principal Investigator (PI) of each Node, one CTP representative from each Node, the Director of the CCTN and the Deputy Director. Each shall have one vote. In the absence of the Principal Investigator or the Node's CTP representative, a designated alternate to the PI or the CTP representative is authorized to vote on their behalf. In addition, the Node Coordinator is authorized to vote on behalf of the absent PI or CTP representative or their alternates.

2. In order to be authorized to vote at a meeting of the Steering Committee, the PI shall provide to the Director, CCTN, in advance of an SC meeting, a written designation naming the CTP representative, the alternate PI, the alternate CTP representative and the Node Coordinator. Unless the Director, CCTN, grants an exception only one alternate will be designated in each category.

3. Voting membership shall expire at the end of the NIDA funding cycle unless the Node is re-funded for the subsequent cycle.

4. Provided that a quorum of the Steering Committee members exists, voting may occur through meetings, conference calls or mail ballots. Unless otherwise indicated in these Bylaws, a majority of those present is required.

SECTION B- Performance Standards

All members supported by the CTN must abide by the policies and procedures of the CTN, including standards for the conduct of clinical trials. Failure to comply with the established performance standards and other policies governing the CTN may result in (1) temporary or permanent discontinuation from participation in CTN clinical trials; (2) NIDA action to reduce the level of funding; or (3) termination of funding.

ARTICLE V - Governing Bodies and Leadership

SECTION A - The Steering Committee

1. The Steering Committee (SC) is comprised of (a) the Principal Investigator and a CTP representative from each Node and (b) CCTN Director and Deputy Director.
2. The CCTN Director shall serve as Chair of the SC unless the Director vacates the position and the SC members select a new Chair by two-thirds vote; and, the NIDA Director approves such selection.
3. Until Node funding expires, each Node shall continue to be represented on the SC by the PI and a CTP representative.

4. The SC constitutes the primary governing body of the CTN. It is the policy of the SC to exert all reasonable efforts to develop consensus on major scientific, management and organizational issues confronting the SC. If consensus cannot be reached after reasonable efforts, the SC chair can request a vote on the issue. In such event, decisions will be determined by majority vote of the Steering Committee, except when the SC delegates this authority to the Executive Committee in Section B of this document.

   Specific responsibilities include:

   a) Review and approve the research agenda of the CTN;
   b) Formulate and monitor policies and procedures guiding the research activities,
   c) Facilitate communications within the CTN as well as with the greater scientific community and the public.

5. To implement the functions of the CTN, the SC may form such committees, subcommittees, working groups and advisory boards as are necessary to carry out the goals of the CTN.

SECTION B - The Executive Committee (EC)

1. The Executive Committee is comprised of 4 Principal Investigators, 4 CTP representatives (all from SC membership) and the CCTN Director. They will further the vision of the CTN as defined by the SC, ensure effective communication and collaboration between the Coordinating Committees (CC) and provide leadership to the CCs, set the agenda for SC meetings and render decisions on behalf of the SC to advance, in a timely manner, the business of the CTN.

2. The EC members are elected from among the SC as follows:
   a. Two (2) at large members are elected by majority vote, one PI and one CTP.
   b. Six (6) members elected by majority vote, 2 each (a PI and CTP) from each Coordinating Committee.
   c. The SC will vote for the 2 at large members first, then for the 6 remaining members after voting results are published.
   d. A PI and CTP representative from the same Node shall not serve on the EC.
   e. The EC members will serve for 2 or 3-year terms, as determined by the EC.
   f. Quorum and voting requirements of the EC shall be the same as for the SC.
3. The CCTN Director shall serve as Chair of the EC, unless the Director vacates the position and the EC members select a new Chair by two-thirds vote and the NIDA Director approves such selection.

SECTION C - The Coordinating Committees (CC)

1. There shall be three CCs each comprised of equal numbers of Principal Investigators and CTP representatives selected from the Steering Committee; provided however, that no CC shall be comprised of less than four members. A representative from the CCTN shall serve on each CC as co-chair and will be selected by the Director, CCTN.
2. SC members will volunteer to serve on each CC.
3. Membership on the CC will be 2 or 3 years, as determined by the CC.
4. The CC shall select 2 individuals, one PI and one CTP who will serve along with the CCTN representative as the Co-Chairs of the CC.
5. Specific responsibilities include the following for each CC:
    a. Portfolio Coordinating Committee (PCC)
        i. Coordinates the Concept & Protocol Review, Common Assessment Battery and Design & Analysis subcommittees.
        ii. Recommends selection criteria for concepts.
        iii. Recommends research portfolio strategy.
        iv. Reviews and assesses protocol progress from concept approval to implementation (V2).
        iii. Assists Lead Investigators with protocol development issues (Add, Jose)
    b. Operations Coordinating Committee (OCC)
        i. Coordinates the Training, Quality Assurance, Data Management & Analysis, and Regulatory Affairs subcommittees.
        ii. Reviews and assesses protocol progress from implementation (V2 to publication)
        iii. Assists Lead Investigators with protocol implementation issues
    c. External Affairs Coordinating Committee (EACC)
        i. Coordinates the Publications and Dissemination Subcommittees and the Research Liaison Group.
        ii. Sets both internal and external communications policies and serves as the primary committee for public relations and external communications.

ARTICLE VI - Meeting Requirements and Parliamentary Procedures

A. The full SC and the Coordinating Committees shall meet face to face at least two times per year, and will engage in conference calls as needed.
B. The Executive Committee shall meet face to face at least three times per year, and will meet via conference calls at least monthly
C. A quorum shall consist of 50% plus 1 of the appointed members present at the meeting or conference calls.
D. The CTN shall be governed by these Bylaws, the Cooperative Agreement award, as duly amended and the Policies and Procedures of the SC. The rules contained in the current edition of Robert's Rules of Order Newly Revised shall govern the CTN in all cases to which they are applicable and in which they are not inconsistent with these bylaws and

any special rules of order the CTN may adopt. To the extent not inconsistent with anything contained herein, the SC will follow SOP-GN-002, Parliamentary Procedures.

ARTICLE VII - Scientific Misconduct

The CTN complies with Public Health Service regulations and polices for handling misconduct in research as set forth in 42 CFR part 50, subpart A.

ARTICLE VIII - Conflict of Interest

The CTN members shall comply with the financial disclosure and conflict of interest policy and guidelines of their institutions and the Conflict of Interest policy approved by the Steering Committee.

ARTICLE IX - Ratification of and Amendments to the Bylaws

A. A two-thirds vote of the Steering Committee shall be required to ratify the Bylaws, which shall take effect immediately upon ratification, unless a later effective date is voted.
B. These Bylaws may be amended at any regularly scheduled meeting of the Steering Committee voting members. Proposed amendments to the Bylaws shall be submitted in writing to the Executive Committee by any voting member of the CTN at least 30 days prior to a regularly scheduled meeting of the CTN Steering Committee.
C. The Executive Committee will place the proposed amendment on the agenda of their next meeting or conference call and will distribute the proposed amendment to their members prior to the meeting/call. A majority vote of the Executive Committee in favor of the amendment shall be required to send the proposed amendment to the SC voting members for ratification.
D. After approval of the proposed amendment by the Executive Committee, the proposed amendment will be distributed to the SC voting members at least (7) days before their next regularly scheduled meeting.
E. A two-third vote of the SC voting members present shall be required for ratification of the proposed amendment. Amendments will become effective immediately upon their ratification, unless a later ratification date is voted.