

# **National Drug Abuse Treatment Clinical Trials Network**

## **By-Laws**

### **ARTICLE I - Name**

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

### **ARTICLE II - Objectives and Purposes**

A. To bridge the gap between practice and research by conducting 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. To facilitate adoption of CTN tested and successful interventions within the CTN and to provide expert support to other components of the National Institute on Drug Abuse (NIDA) and the Public Health Service in the timely transfer of research results to clinicians, providers, their patients and 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 (U10 grants) between academic research institutions, NIDA and is administered by the Center for Clinical Trials Network (CCTN) of NIDA.

### **Network Structure**

Clinical Trials Network (CTN). A collaborative group of clinical research and training Nodes working collaboratively with NIDA to conduct multi-site clinical trials on promising behavioral, pharmacological or integrated treatments, and serve as a platform for clinical research and training.

NIDA CCTN Office. An office reporting directly to the Director, 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 coordinates and arranges 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. The principal investigator(s) 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 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) has a major role in setting the scientific agenda of the CTN in conjunction with NIDA; reviews and approves final protocols for implementation; determines and revises, as necessary, the CTN governance; elects members and oversees the operations of the Executive Committee and the Research Development Committee; and oversees the performance of the Publications and Research Utilization Committee. Members of the Steering Committee participate in CTN committees and task forces, as needed, based upon expertise, interest, and Node budget.

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. To minimize delay and provide continuity, this board can be combined with a DSMB (see below) for a study.

Data and Safety Monitoring Board (DSMB). The DSMB is an independent expert board, appointed by and reporting to the Director of CCTN that oversees and monitors the conduct of the clinical trials to ensure the safety of participants and the validity and integrity of data for each study. The DSMB also makes an independent assessment of the interventions under study and whether or not any trial undertaken in the CTN will continue. One or more NIDA staff serves as a non-voting administrator of the DSMB. One or more DSMBs may be appointed to oversee CTN clinical trials.

CTN Ad hoc Advisory Panels. The Director of NIDA may appoint expert panels to advise the Institute and CCTN on specific scientific directions or trials.

Clinical Coordinating Center (CCC). An organization selected by NIDA to provide centralized support for regulatory functions and requirements, protocol monitoring, training of staff involved in research studies, pharmaceutical supply services, drug testing and analytical laboratory services, and protocol development.

Data and Statistics Center (DSC). An organization selected by NIDA to provide centralized support for collecting, managing, and storing study data; designing and performing statistical analyses; reviewing and monitoring data quality; monitoring trial progress; preparing reports for the DSMB and CCTN; and protocol development.

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

## **ARTICLE IV – Organizational Leadership of the CTN**

### **SECTION A - The Steering Committee**

1. The Steering Committee (SC) comprises the following voting members: (a) the Principal Investigator (PI) of the U10 grant and a CTP representative from each Node, (b) CCTN Director or Deputy Director, and (c) representatives from the NIDA contracted Coordinating Centers, which representatives shall be approved by the Director, CCTN or designee.
2. Each Node shall determine the term of service and rotation policy on the SC for the PI and CTP representatives.
3. The PI and/or the CTP representative may designate alternates to sit and vote at meetings of the SC provided that the individuals are of sufficient stature and leadership in the organization they represent.
4. There shall be a Chair and a Vice-chair elected among the membership of the SC who shall serve for a term of one year. The Chair and/or Vice-chair may serve more than one term. Candidates for the positions shall be self-nominated from the SC. The Chair will be selected from among the PI members and the Vice-chair from among CTP members. Neither the Chair nor the Vice-chair may serve on the EC or RDC.
5. The Steering Committee shall meet face-to-face two times each year, and by conference call, as necessary. The time and/or place of meetings and conference calls shall be at the recommendation of the Chair with the concurrence of the Director, CCTN.
6. Provided that a quorum of the SC members exists, voting may occur through meetings, conference calls, or mail ballots. Unless otherwise indicated in these Bylaws, a majority vote of those present is required.

### **SC Roles and Responsibilities**

The roles and responsibilities of the SC are set forth in Article III, Organization.

### **SECTION B - The Executive Committee (EC)**

1. The Executive Committee comprises 5 Principal Investigators (PIs), 5 CTP representatives elected by and from the SC membership, the CCTN Director or Deputy Director, and one member from each Coordinating Center. The members from the Coordinating Centers are non-voting *ex officio*, and will be selected in consultation with the Director, CCTN.
2. SC candidates for the Executive Committee shall be self-nominated. Candidates must commit to the considerable time and energy that service on the EC will require.
3. The term of service on the EC shall be for 2 or 3 years as decided by the EC to ensure orderly rotation depending upon the Node funding cycle and other factors. Vacancies will be filled by special election.
4. The EC shall meet by telephone conference calls on a monthly basis, by face-to-face quarterly meetings at a time and place approved by the Director, CCTN and such other times as the Chair deems necessary.
5. PI and CTP representatives from the same Node shall not serve on the EC.
6. Quorum and voting requirements of the EC shall be the same as for the SC.
7. The CCTN Director or Deputy Director shall serve as the Chair of the EC. If the Chair position is vacated by a NIDA member, EC members shall select a new Chair by two-thirds vote, subject to the approval of the NIDA Director.
8. The EC is delegated authority to act on behalf of and for the SC in order to further the business of the CTN.

## **EC Roles and Responsibilities**

1. Renders decisions on behalf of the SC to advance, in a timely manner the business of the CTN.
2. Through protocol oversight, recommends to CCTN actions necessary to keep protocols on track.
3. Receives and acts upon reports from CCTN and the Coordinating Centers.
4. Provides oversight of the Publications Committee, Research Utilization Committee and the Research Development committee.
5. Reports to SC at meetings and through EC minutes.
6. Ensures effective communication and collaboration among Nodes.

## **SECTION C – Research Development Committee (RDC)**

1. RDC membership will be composed of members from the SC and elected by SC members. Candidates shall self-nominate. Members must commit time and energy to the RDC and be knowledgeable about the treatment needs of the field and effective approaches to meet those needs.
2. An RDC member cannot serve on the EC and an EC member cannot serve on the RDC.
3. RDC membership shall be composed of 4 PIs and 4 CTPs, and a designee of the NIDA director. The Chair will be elected among the RDC membership.
4. The RDC may appoint Ad hoc Task forces to address specific areas of investigation.
5. The term of the RDC members shall be approximately 2 years based upon the generation period for new projects.
6. Report to EC quarterly or as needed.

### **RDC Roles and Responsibilities:**

1. Plans jointly with NIDA for a strategic CTN research agenda.
2. Coordinates “brainstorming” workshops with a wide range of experts to formulate research questions that capture the unique scientific opportunities and address critical public health needs.
3. Establishes Ad hoc Task forces to address specific areas of need. These task forces will be time-limited and focused on specific tasks.
4. Prioritizes research projects and establishes protocol project teams for EC and SC consideration and approval.
5. Actively promotes the use of CTN as a research and training platform.

## **SECTION D – Research Utilization Committee (RUC)**

1. Each Node shall select one Node Research Utilization Coordinator (NRUC). The NRUC identifies candidates for membership on the RUC who possess an expertise and interest in dissemination.
2. The NRUC could serve on the RUC but others could serve as well. Members of the RUC can be selected from individuals representing a wide range of interests including the EC,

SC (but members need not serve on the SC), and other individuals affiliated with the Node.

3. The RUC shall be composed of 8 members who are elected by the NRUCs and one member from the CCTN. The term of service is 2 years. A chair shall be elected from among the members.
4. The RUC will communicate with NRUCs through e-mail and conference calls.
5. The RUC may establish time limited Ad hoc task forces that bring in expertise not available in the RUC or the NRUCs.

#### **Roles and Responsibilities of the RUC:**

1. Facilitates adoption of CTN-tested and successful interventions within the CTN.
2. Facilitates sharing of cost effective dissemination strategies among Nodes, Blending Teams, or Federal and State partners.
3. Assists Nodes in developing internal dissemination projects and developing partnerships for internal dissemination.
4. Tracks and describes dissemination activities within the CTN.
5. Promotes dissemination research using CTN as a platform.
6. Report to EC as required.

#### **SECTION E – Publication Committee (PC):**

1. Each Node PI shall designate at least one person to be part of a reviewer pool for the Publication Committee. To the extent feasible, the reviewer pool should be balanced between researchers and providers. A reviewer should possess the interest, expertise, and willingness/commitment to review, on a timely basis, publication materials, and could include representatives from the CCTN and the SC.
2. The PC shall be composed of 7 members, including one from the CCTN and one from the SC. PC members are self-nominated and elected by the EC, with a service term of 2 years. The Chair of the PC shall be elected by the PC members.
3. The publication reviewers could serve on the PC, but others could serve as well. Members of the PC can be selected from individuals representing a wide range of expertise including the EC and SC.
4. The PC shall determine the number of reviewers who will review each publication draft based upon the complexity of the subject matter and other factors.
5. The PC shall communicate between themselves and the publication reviewers through e-mails and conference calls.
6. The PC can form time limited ad hoc task forces that bring in expertise not available in the reviewers pool.

#### **Roles and Responsibilities of the Publication Committee:**

1. Ensures the publication of timely and quality CTN results through:
  - a. Reviewing protocol publication plans, including timelines and journal selections.
  - b. Arbitrating publication disputes, e.g., ranking of authors on a CTN-related paper.
  - c. Reviewing manuscripts to ensure appropriateness and quality of CTN publication.

- d. Interacting with CTN publication authors to facilitate and ensure timely publication of study results.
2. Identify and promote publication opportunities.
3. Identify meetings of professional societies in which the CTN can showcase its research results.
4. Encourage and coach junior researchers and practitioners to publish through:
  - a. Facilitating data sharing to generate additional publications with the CTN database.
  - b. Conducting workshops to coach junior researchers and practitioners on secondary data analysis and manuscript writing.
5. Report to EC as required.

## **SECTION F - Ad hoc Task Forces (AHTs)**

### **Principles:**

1. AHTs are appointed by and report to the CTN committee who establishes the AHT e.g., SC, EC, RDC, RUC, PC.
2. They shall be established for a specified purpose that the appointing committee itself cannot address and are not intended to be an on-going activity.
3. The appointing committee defines AHT goals, work products, and timelines.
4. AHT membership shall be broadly based so that there is an opportunity for full input and the benefit of special expertise by the greater CTN.
5. Communicates to SC and CCTN through the appointing committee.
6. Sunsets at a specifically stated time or upon completion of the task.

## **ARTICLE V – Procedures**

- A. For meetings of the SC and EC, a quorum shall consist of 50% plus one of the appointed members. Voting shall be by a simple majority unless otherwise indicated in these Bylaws.
- B. The CTN shall be governed by these Bylaws and the Cooperative Agreement award. Should there be an inconsistency between those documents; the terms of the Cooperative Agreement shall govern.

## **ARTICLE VI – Scientific Misconduct**

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

## **ARTICLE VII – Performance Standards**

All 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 (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 VIII – Conflict of Interest**

The CTN shall comply with the financial disclosure and conflict of interest policy and guidelines of their institutions.

## **ARTICLE IX - Ratification of and Amendments to the Bylaws**

- A. A vote of at least two-thirds of the SC members attending a regularly scheduled meeting of the CTN is required to ratify the Bylaws.
- 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 Steering Committee, within a time that the EC considers reasonable for consideration of the amendment.
- C. The Executive Committee will submit the proposed amendment to the SC voting members at least 7 days before their next regularly scheduled meeting, with a statement of the EC's position on the amendment. The Bylaws may be amended by a two-thirds vote of the SC members attending a regularly scheduled meeting of the CTN.