The organization model described below provides for the efficient conduct of complicated multi-center and multi-node research projects. The organization model also provides for maximum participation across the participating nodes and for assurance that the project is truly a cooperative activity among the parties of the CTN.

Key to the conduct of each project is the selection of a lead investigator by the CTN Steering Committee to provide scientific oversight for a specific research project, under a protocol approved by NIDA and by the CTN Steering committee. The lead investigator is acting in this activity on behalf of the Steering Committee.

The Steering Committee will name a project team for each approved project.

The lead investigator will:

1) Nominate the members of the research project team for final approval by NIDA and the Steering Committee.
2) Lead the approved project team and provide scientific oversight to it in the design and conduct of the project.
3) Coordinate the work of the project team with the subcommittees of the CTN, as appropriate.
4) Report periodically to the Steering committee on the progress of the project.
5) Guide preparation and publication of reports of study results under the CTN publication policies and procedures.

The research project team will:

1) Comprise at least two scientific collaborators from nodes other than the lead investigators node, one or more treatment program collaborators, one or more NIDA scientific collaborators, other scientific, research management, and technical experts from inside or outside the CTN as needed.
2) Be responsible for the design of the project, in conjunction with research design and statistical expertise available on the CTN Data Committee.
3) Oversee the conduct of the project.
4) Provide the peer-review for quality assurance of the project, in conjunction with the CTN Quality Assurance Committee.
5) Design the statistical analysis needed to carry out the project, in conjunction with the CTN Data Committee.
6) Work on the publications from the project, in conjunction with the CTN Publications Committee.
7) Identify training needs, in conjunction with the CTN Training Subcommittee, and ensure these needs are met.

One of the members of the project team will be named project director. The project director will:

1) Be responsible for managing the conduct of the project under the scientific direction of the lead investigator and working with other members of the project team.
2) Maintain records and documents of the project.
3) Prepare periodic reports of the projects progress for the Steering Committee and to meet any regulatory needs of the project.
4) Coordinate implementation of the research project working with identified node project coordinators in each participating node.

The node project coordinators (one from each node) will:

1) Participate in the design of the project implementation plan.
2) Recruit participating CTP within their node.
3) Report progress on the nodes activities for the project to the project manager.
4) Coordinate communications between the project and all staff in the node.
5) Coordinate quality assurance activities within the node, in conjunction with the project manager and the CTN Quality Assurance Committee.

Supplement
CTN Protocol Development Team Key Roles and Responsibilities

Lead Investigator (LI):   Provide project leadership in:

1. Developing and implementing the protocol:
   a. Coordinate team membership and tasks
   b. Complete protocol
   c. Ensure preparation of operational, data management, QA and training plans
   d. Obtain medications and identify supply/laboratory/pharmacy centers
   e. Complete regulatory documentation & Investigator's Brochure
   f. Provide scientific support during study performance
   g. Reviews adverse and serious adverse effects
2. Preparing project budget
3. Analyzing the data
4. Publishing the study results
5. Adhering to regulatory requirements
6. Ensuring communications regarding human subjects safety

Project Director (PD):   Key person in translating the science into the implementation of protocols. Work closely with the LI and the Node Project Coordinator (NPC) to direct and organize all protocol implementation activities; **ensuring**:

1. The protocol starts on time according to timeline
   a. Prepares SOPs
   b. Develops data management
   c. Complies with regulatory requirements
   d. Incorporates protocol revisions
   e. Directs and coordinates trial activities for pre-post protocol implementation, including training
2. The identification of inconsistencies between resource requirements, allocations and budget
3. Early recognition of potential problems
   a. Troubleshoots problems when required
   b. Provides guidance regarding study requirements
   c. Provides system for missing or inaccurate data
4. The integrity of study results
   a. Ensures adherence to the protocol
   b. Reviews study performance across the nodes
5. The safety/well being of subjects
   a. Ensures IRB reviews the protocol & informed consent prior to implementation
   b. Reviews node reports regarding informed consent & AE/SAE issues

6. Timely communication to LI, PI, Project Teams, Steering Committee & Subcommittees and NIDA

NIDA Scientific Collaborator: As a protocol team member:

1. Participates in all scientific activities regarding protocol design, development and data analysis
2. Act as liaison between the project team and NIDA to leverage resources and communicate program policies
3. Ensure all protocol review comments are addressed by the PI or incorporated in final version.

Other Scientific Collaborators (Co-LI): As protocol team members:

1. Participates in all scientific activities regarding protocol design, development and data analysis

Node Project Coordinator (NC):   Key person and conduit between the Project Director (PD) and the-NODE. Represents (a) the RRTC PI in all fiscal and administrative matters; and (b) the interests of the protocol-participating CTPs. Work closely with the PD to implement protocols on issues of:

1. The identification of inconsistencies between resource requirements, allocations and budget at each NODE.
2. Early recognition of potential problems
3. Coordination of data collection and expedite submission to central database
4. The integrity of study results
5. The safety/well being of subjects

CTP Participants:

1. Participate in the design and development of the protocol
2. Participate in the protocol review meetings
3. Conduct clinical trials according to the protocol
4. Participate in the data analysis and publication

GUIDELINE FOR PROTOCOL OPERATION

The Node Protocol Project Coordinator is the key person(s) for a smooth protocol implementation and operation. This individual will work closely with the Protocol Director, Protocol Project Team, Lead Investigator, Node Principal Investigators, and Node staff to coordinate the Node protocol implementation and operation tasks. Some of the tasks are the following (also, see figure one attached):

    a. CTP assessment for protocol feasibility
    b. Protocol review and completion
    c. Completion of local QA and training plans
    d. Trial activities (such as supplies, medications, laboratory testing, etc.)
    e. Data management issues
    f. Training of participating staff
    g. Communication between the NODE and PD before, during and after protocol implementation
    h. Troubleshooting problems when required
    i. Study requirements guidance
    j. Implementing system for missing or inaccurate data
    k. Study monitoring
    l. Compliance with protocol and regulatory requirements
    m. Progress and performance reports as needed
    n. IRB approval of protocol and informed consent prior to implementation
    o. IRB review of any amendments
    p. Study cases for signed informed consent form and AE/SAE
    q. Timely reporting of AE/SAE to officials (such as IRB, PD, PI, NIDA, FDA, etc.)

CTN Protocol-Specific Project Organization

CTN STEERING / OPERATIONS COMMITTEE

Lead Investigator

Collaborators
~2 Other Nodes
~NIDA
~Other Experts

Protocol Project Director

Node Project Coordinators

CTPs

CTPs

CTPs

CTPs

CTPs

Protocol Development

Data Management

Regulatory Affairs

Training

Quality Assurance

Data

Regulatory

Training

Quality