

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

## **CTN as a Platform**

### **Introduction**

Three important ways to use the CTN are: to conduct ancillary studies in connection with CTN protocols; to utilize CTN Node facilities as a platform for investigations; and for Nodes to serve as home bases for NIH Training Centers and individual researchers who have NIH fellowships or career development awards.

### **Definitions**

**Ancillary investigations:** These projects may be conducted at one or more sites adjunctive to a CTN trial, described as the CTN parent study. Examples of potential research initiatives include but are not necessarily limited to a) addition of related research methods or questions, b) economic analyses including costs and cost-effectiveness, c) health services research on the organization, delivery or adoption of treatment, d) genetic studies, and e) follow-up studies on subjects beyond the parameters of the parent trial. These investigations would be funded from sources outside the CTN. It is expected that all proposals are reviewed and approved by a nationally recognized scientific panel (such as NIH IRG) before implementation.

**Platform studies:** These projects may be conducted at one or more sites independent of a CTN trial and would be funded from sources outside the CTN.

### **Scope**

This policy applies to all scientific investigations that require access to the CTN infrastructure. Proposed studies will be referred to the Executive Committee and NIDA CCTN for preliminary approval. Proposals that do not request approval through this policy may be denied access to the CTN infrastructure.

### **Responsibilities**

Investigators seeking to use CTN infrastructure, including the participating clinical treatment programs, practitioners, research staff, RRTC resources, or patients are expected to follow this policy to gain permission for the investigation and to report study progress and findings to the CTN. The principal investigator of any external investigation has the primary responsibility for the implementation and timing of a specific research program in collaboration with the participating Nodes, as well as the study team for a parent study, if applicable. Investigators must follow and comply with all applicable Human Subjects Protection and clinical research regulations (local, State and Federal), and obtain IRB approval prior to implementing any study.

## **Procedure for Submission, Approval and Coordination of Platform Studies**

### **A. Ancillary investigations.**

It is imperative that studies that will be added onto a CTN clinical trial be planned well in advance with the support of the investigative team of the parent study. The timelines for implementation, collection of data, progress, and management of the parent study take precedence.

1. Investigators requesting an ancillary study must prepare and submit:
  - a) Approval by the parent study Executive Committee (via Chair/Lead Investigator)
  - b) A proposal describing rationale, methodology and CTN resources involved. Please include any additional assessments required, and any data needed from the parent study.
  - c) Endorsement by Node PI of any CTPs expected to participate
  - d) A clear statement of the impact on the parent CTN study, including, but not limited to:
    1. overall timeline
    2. recruitment
    3. human subjects issues
    4. data collection
  - e) Plan for data sharing (expected schedules, dataset format, conditions for its use, mode of data sharing, necessity of data use agreement, etc.).
  - f) Statement regarding the Data and Safety Monitoring Plan. Studies added on to existing trials would be reported to the CCTN DSMB for the parent study.
  - g) Agreement to work collaboratively with the parent study, to abide by all study policies and data provisions, and to cite the role of the CTN in any publications
2. If study is already funded, a summary of the scientific review with approval recommendation.
3. If the study will seek funding, provide information regarding funding source (see B 2 c below) and timing.
4. If the proposed study is for a genetics study, investigators need to comply with the procedures set forth at:  
[http://www.nida.nih.gov/about/organization/genetics/FAQ\\_CTN.html](http://www.nida.nih.gov/about/organization/genetics/FAQ_CTN.html).
5. The items required above shall be submitted to CCTN and forwarded to the Executive Committee (EC) to be considered for approval. The nature and extent of review procedures will depend on the scope, complexity and content of each request.
  - a) If the study already is funded, the EC will review the submitted documentation. Once approved by EC, NIDA CCTN Director will review and provide final approval for implementation.
  - b) If the study is seeking funding, the EC will review the proposal and recommend that NIDA CCTN provide a letter of endorsement to use the CTN as a platform. The endorsement letter will be forwarded to the investigator within one week of approval. Once the investigator receives funding, he/she should contact the CCTN Director to coordinate the implementation of the study. If funding is from non-NIH sources, the investigator must provide copy of peer review summary, per A 2 above.

6. Investigators of the ancillary study must recognize that the parent study would be implemented according to its own timeline. In addition, monitoring of the parent study may result in protocol changes, elimination of sites, or even early termination.
7. The CCTN will notify investigators of the willingness to provide access to the parent trial for the ancillary study. It is likely that peer review will follow this step. The investigators should provide a summary of the reviewer's comments to CCTN. Final implementation of the ancillary study will depend on provision of adequate funding for the study and program priorities within NIDA.
8. The Investigators of the ancillary study must sub-contract with the CTN Coordinating Centers:
  - a) Data & Statistical Center regarding data management, collection, transfer, etc. and expectations for final data set.
  - b) If necessary, with the Clinical Coordinating Center regarding services that may be provided (e.g. monitoring, regulatory support, supplies, etc.).
9. Study support: It is required that the investigators of the ancillary study will be available to the parent study team and participating sites to assist with all aspects related to their ancillary study (such as preparation, IRB submission, study management, etc.).
10. The investigators of the ancillary study must conduct the study according to federal, state and local regulations and protections of human subjects. NIDA CCTN reserves the right to audit the study prior to delivery of requested data set.
11. Publications: Investigators should acknowledge the role of the CTN in any papers prepared for publication. Copies of publications should be sent to the chairs of the Publications Committee.
12. Reporting: Investigators will provide semi-annual reports to the EC that summarize study implementation, enrollment, expected completion date, and list study publications; reports will continue until the principal investigator sends a formal notice of study completion to the EC.

## **B. Platform studies**

1. Requests for permission to access the CTN infrastructure (other than ongoing trials) shall be e-mailed to NIDA CCTN Director.
2. Submission Procedures: Requests should include the following:
  - a. Brief description of the proposed study
  - b. CTN facilities or personnel involved
  - c. Funding source(s). Announcement # and title (For Example: RFA-DA XXX from NIDA, titled ".....")

3. NIDA CCTN Director will provide a letter of endorsement to use the CTN as a platform to the requesting investigator within one (1) week of receipt.
4. The externally funded protocol must fully cover all costs associated with the investigation, including expenses (if any) for the CTN staff.
5. Publications: Investigators should acknowledge the role of the CTN in any papers prepared for publication. Copies of publications should be sent to the chairs of the Publications Committee.

### **C. Research Training Scientists**

While the NIDA CCTN encourages and supports the affiliation of individually funded scholars or training centers within the CTN Nodes, it remains the sole prerogative of the Node leadership whether or not to incorporate the individuals or centers. Scientists who are applying for an NIH-funded training award should contact the program director of the Node for information on local review procedures regarding scholars taking up residence and training centers being located at the Node.

If a letter of endorsement to use the CTN as a platform is needed, then the procedures for obtaining the letter are the same as B (Platform Studies) above.