CTN-POL-020	**CTP PARTICIPATION IN CTN PROTOCOLS**	Date Approved: 16 Jul 01
Approved by: SC	Date Revised: Revised by:	Page 1 of 3

I. Introduction: Decisions about CTP participation in protocols involve communication and decision-making among three individuals: the protocol lead investigator (LI), the Node PI, and the CTP considering participation. The policies and procedures outlined below are designed to assist these three individuals to make decisions in a fair and consistent manner. The policies and procedures are applicable to both large and small studies within the CTN.

II. Policy:

1. The CTN should seek to locate protocols in diverse settings so as to evaluate the applicability and effectiveness of interventions across a variety of settings. Such diversity includes such dimensions as small vs. large program, rural/ urban setting, race/ethnicity of patients, gender of patients, and region of the country.

2. Decisions about CTP participation must take into account the limited resources of both the participating nodes and the lead node.

3. The Lead Investigator and Protocol Team have responsibility for the scientific integrity of the study, and the Lead Investigator has responsibility for lead node resources that will be expended in coordinating the protocol. Therefore, the Lead Investigator, with the Protocol Team (following input from Concept Review, NIDA, the design and analysis subcommittee, and the protocol review process), should determine how many and which CTPs may participate.

4. Each node decides, through their own processes, what CTPs to put forward for protocols. Since, some nodes have more CTPs than others, protocol participation decisions should seek to distribute protocol opportunities fairly across nodes as well as CTPs, e.g., by not penalizing smaller nodes.

5. The CTN should seek to conduct protocols *within* the network of CTPs that are involved in its nodes. Alternate mechanisms of funding should be sought for studies with requirements that cannot be met in these programs.

6. While decisions may be made about a CTP s participation based on its prior or current involvement in another protocol, CTPs should not be limited regarding the number of protocols to which they may *apply*.

7. Decisions on what studies to pursue in the CTN should be truly bi-directional. CTP input about their ability to participate and interest in participating in concepts would enhance bi-directionality as regards determination of the CTN research agenda and portfolio.

III. Procedures

1. Concepts and protocols will address diversity of setting so as to assure relevance of research findings to the field. In concept proposals this can be addressed in the significance section and in discussing the objectives of the research and scored under

Public Health Significance. [This entails modifications to Concept Development Policy.]

2. The design and analysis committee will review how well the plan for CTP participation meets the objectives of the research and provides needed power to address those objectives.

3. After concept submission, and before concept scoring by the Concept Review Subcommittee, concepts will be circulated to CTPs by all nodes. Nodes will provide a count of CTPs interested in participating in each protocol to the Concept Review Subcommittee prior to concept scoring. Concept review will include points under feasibility for sufficiency of CTP interest. [This also entails modifications to Concept Development Policy.] It is expected that each node will determine how to most efficiently accomplish the polling process. While potentially cumbersome, this process would assure bi-directionality and the ability of protocols to move forward after approval. To increase a concept s chances of success, it is encouraged that, in developing concepts, LIs obtain informal response from a sample of CTPs within and outside their nodes.

4. For all types of studies (e.g., large and small studies) CTP interest in a study will be formalized through a written application to the LI/Protocol Team from a node PI and interested CTP addressing the issues listed in item 5, below. The LI will provide feedback to those nodes that have put forward a CTP, regarding reasons for selecting or not selecting a CTP that has applied.

5. If more CTPs have been put forward by their nodes for participation in a study than are needed to meet its objectives, the LI is responsible for determining which CTPs can participate. Factors that might be taken into consideration could include:
   a. Degree to which a CTP s participation enhances the relevance of the study to clinical practice (e.g., inclusion of rural programs, diversity of patients, geographic distribution).
   b. Availability of special and minority populations and need to include them in the research.
   c. Participation in the study would represent an enhancement to the CTP by expanding the future capacity of the CTP to provide a wider range of services that would benefit the patients.
   d. Involvement of the CTP in development of the protocol.
   e. Pending, current & prior protocol participation of the CTP.
   f. Prior protocol participation of the node and node size.
   g. Limitations on future opportunities for the CTP (i.e., if some CTPs are more limited in the kind of protocol they can join, and others have more flexibility, priority would be given to the CTP that is presumed to have fewer options).

6. If conflicts over CTP participation can not be resolved by the LI and the nodes involved, an ad hoc group composed of one PI from the SC (not the LI and not from an involved node), one CTP SC representative (also from a node not involved), and one SC member from NIDA will be formed by NIDA to make a decision. This process can be initiated by a CTP or by the LI/Protocol Team. This ad hoc group will recommend a decision to the Operations Committee.