SOP-PR-001	**CONCEPT SUBMISSION AND REVIEW**	Date Approved:
Approved by: SC	Date Revised: Sep 03 Revised by: PCC	Page 1 of 6

Purpose

CTN conducts research that examines the effectiveness of treatment interventions in real world community drug abuse treatment settings. The purpose of a concept proposal is to present sufficient background and rationale to justify utilizing CTN resources to conduct a particular study within the CTN network.

Concept Submissions

The outline below emphasizes the most relevant aspects of a proposal at the concept stage. These include clinical need/public health significance, scientific merit/stage of science, feasibility and sustainability. The idea is that detailed protocol development will follow for approved concepts. It should be noted that the suggestions presented in this document for the content, length and format of CTN protocol concept submissions are meant to serve as guidelines rather than rigid standards for concept submissions. The main point is that the concept submission should present a compelling case for why the study is needed and for why CTN is the right place to pursue this particular concept.

I. Concept Content

A. Topics

1. Clinical significance. The first topic to be addressed is clinical significance. How does this proposal address current needs and research priorities? Why is it well suited for conduct in the CTN? If successful, what is its potential to enhance clinical practice? What is the potential for transferability and sustainability should the study have positive findings? This section should present a compelling case for why this study is needed, and why the study should be carried out in the CTN.

2. Prior research base or experience/knowledge. The concept proposal should include a detailed presentation of the background research/clinical information that supports the intervention proposed for study. Where there is an extensive research base, this presentation should indicate the number of studies that have been conducted and should include a detailed summary of previous studies, including study designs, study results and potential generalizability of previous study results to CTN. Actual data from original studies should be presented in tables or graphs. This section should also contain a detailed discussion of competing intervention models that exist for addressing the targeted clinical problem. This includes the research base for competing models, and a rationale supporting choice of the proposed model over the others. A discussion of how the proposal adheres to or departs from the original efficacy research, and the rationale for any revisions should be included.

   When the concept is generated from clinical experience rather than efficacy data from research studies, the extent of knowledge and experience with the intervention should be provided, with as much detail or data as possible. Examples would be 1) previous research supporting modalities closely related to that proposed in the concept; 2) concepts proposing

to evaluate treatment modalities already in widespread use that may not have been previously evaluated in traditional efficacy studies and 3) concepts that propose modifications of efficacy based treatment modalities to make them more feasible, generalizable, cost-effective, compatible or sustainable in CTN.

3.

3. Study questions, design and sample size. This relatively brief section should specify the study question clearly and without ambiguity, along with the primary study hypothesis. This section should indicate the anticipated research design, target population and the primary outcome measures. (Study design, especially the number and type of comparison groups, should be informed by the extent of supporting research.) This section should include a clear explanation supporting how the study design and primary outcome measures will answer the research question posed and how the study hypotheses can be accepted or rejected based on data analysis. The effect size of the proposed intervention should be gathered from previous studies or clinical experience. Clinical significance of the effect size should be explained as well as implications for sample size needed in a CTN study.

4. Feasibility. A section on feasibility should address several important issues including: a) the likely availability of the targeted population within CTN clinics, b) the availability of a developed training manual (for behavioral interventions) and what is required to train clinicians in the intervention, c) training experience of the concept workgroup members with this type of therapy or plans to involve experienced trainers and d) a preliminary estimate of resource and budget requirements.

B. Concept Organization

The concept proposal should be a maximum of 10 pages, excluding references and appendices (with Times 12 point font or equivalent and 1 inch margins all around, single-spaced). Approximations for section page lengths are shown below, and are not intended to be mandatory, but are provided to convey a sense of relative importance:

1. Clinical need and public health significance (0.5-1 page)
2. Research background (up to 3-4 pages)
3. Study hypothesis and design (1-2 pages)
4. Feasibility issues (1-2 pages)

II. Concept and Protocol Review Subcommittee (CPRS)

A. Charge to the CPRS

The charge to the CPRS is to serve as a formal review subcommittee of the CTN SC. The CPRS will perform the initial review of all concepts submitted to NIDA. All concepts will be scored and ranked according to the criteria outlined below. Protocol reviews are largely left to NIDA's external Boards, but may be undertaken by the CPRS on an as-needed basis upon request by the SC, PCC or NIDA (for example, in cases of significant protocol drift during the development phase from the originally approved concept).

B. Composition of the CPRS

As a formal review body, the CPRS will require members who have areas of expertise relevant to performing reviews of concepts and protocols. These areas include, clinical trial methodology, addiction medicine, drug abuse interventions (medication, behavioral treatments), research design, and clinical feasibility and sustainability.

CPRS will be chaired by a NIDA staff person. This review subcommittee will be comprised of representatives from each node. Each node may recommend up to three candidates (including both faculty and CTP members) who represent the node's expertise and vision and who are willing to assume the responsibilities of the review task. This nomination process will provide a pool of available clinicians and university-based researchers. From this pool, one member per node will be selected by the Chair in keeping with the need for specific expertise and clinician/faculty balance. Those not initially selected will remain in the pool of available members who may be called upon to participate in the review of specific concepts/protocols, as the need arises. When expertise in any specific area is needed but such experts do not reside in the CTN, the chair of CPRS may select additional reviewers (who do not need to be CTN members) for their specific expertise on an ad hoc basis.

III. Concept review

A. Call for Concepts

Call for concepts will be initiated periodically by NIDA in collaboration with the PCC. The call may specify research priorities or gaps consistent with NIH/NIDA/CTN goals, and with portfolio balance in the CTN. The goal is to maintain an adequate pipeline of CTN studies, without exceeding CTN manpower and resources.

B. Concept Review: Dimensions of Evaluation

The three review dimensions address public health/clinical needs, scientific background, and feasibility/dissemination; these categories have been given equal weighting. Further specification within each category is provided below. At present, these criteria are largely from the perspective of review for multi-site effectiveness trials. Criteria may be modified in the future to accommodate other types of research.

1. Public health/clinical need

If this intervention works, how important will it be for improving treatment outcomes and/or treatment service delivery? Does the study address gaps in the CTN portfolio or in the drug abuse treatment field?

- Demonstrate public health need
- Demonstrate clinical need and interest (through CTP Caucus and/or Special Interest Group identification of gaps)
- Potential benefit to the population served
- Will advance field of drug abuse treatment

2. Scientific background

What is the stage of development/science behind this intervention?

- More than one controlled clinical trial showing efficacy in drug abusers
- More than one controlled clinical trial showing efficacy in another population
- Small controlled or uncontrolled studies conducted by a single investigator or small effect size demonstrated
- Widespread use and/or clinical observation of beneficial effects
- Study follows logically from background research/experience

3. Feasibility/Transferability/Sustainability

Can this study be implemented in the CTN?

- Target sample available
- Training manual/practice guideline available
- Counselors/therapists easily trained
- Can be implemented in real world settings within constraints of staff, time, and resources
- Acceptable/desirable to clinic staff and patient population
- Can be integrated into clinic culture and treatment options over time

IV. Concept Review Process

A. Review Meetings

CPRS review/discussions should be conducted during face-to-face meetings attached to Steering Committee meetings if possible (depending on the submission schedule). The face-to-face meetings will ensure confidentiality of discussions. In addition, CPRS members should recuse themselves from reviewing concepts for which conflicts of interest exist (use same COI form for PCC members). If it is not possible to hold a CPRS review meeting during the SC meeting, the CPRS review can take place via closed and confidential conference calls.

NIDA will chair and administer the CPRS reviews. The Chair will assign primary reviewers according to the area of expertise required for the specific concept. Reviews will be conducted in accordance with the Concept Review Criteria specified above. These written critiques will be available to applicants after the review is complete.

B. Review Process

1. CPRS will review each concept separately to identify its strengths and weaknesses for each of the three dimensions. In addition, the concepts will be scored to produce a rank ordering of all concepts. The rank-ordered list of concepts along with the write-up of the strengths/weaknesses in each concept will be sent to each member of the Steering Committee.
2. The ranked scores and the review comments on each concept will be submitted to SC members for review; to allow opportunity for comment by the full SC, for consideration by PCC.
3. PCC will select a slate of concepts for further development into protocols based on:
    a. CPRS review and ranking
    b. SC comments
    c. portfolio balance considerations
    d. research priorities as dictated by NIH, NIDA, and the CTN

4. PCC will present their recommendations to SC for approval.
5. Approved concepts will proceed to review by NIDA's Ad-Hoc Oversight Review Board, who will make their recommendations to NIDA.
6. NIDA makes a final decision as to which concepts will go forward on the basis of all the recommendations provided, and issues notification to the LIs.
7. LI assembles the protocol development team and submits the team members qualifications to the PCC for review.
8. PCC works with the LI teams to ensure adequate experience and capabilities for successful protocol development and implementation, both scientifically and administratively. PCC presents their conclusions to the SC.
9. LI and team proceed to protocol development, which will be monitored by PCC.

C. Development and Review Timelines

	Time Allotted
CONCEPT DEVELOPMENT	
Call for concept to concept submission	8 weeks
Total concept development time	**8 weeks**
CPRS Review, Comments to SC	4 weeks
SC Comments to PCC	2 weeks
PCC Review	4 weeks
SC Approval	2 weeks
NIDA Ad-Hoc Oversight Board Review	4 weeks
NIDA Approval	2 weeks
Total concept review time	**18 weeks**
PROTOCOL DEVELOPMENT	
Assembly of LI Team	2 weeks
LI Team Qualification Review	2 weeks
Prepare Version 1	10 weeks
PRB review	4 weeks
PRB comments to LI	2 weeks
Address PRB comments: Version 1a	4 weeks
PRB second review & comments to LI	4 weeks
Address PRB comments: Version 2	2 weeks
DSMB preparation	4 weeks
DSMB review	4 weeks
DSMB Comments to LI	2 weeks
Address DSMB comments: Version 3	2 weeks
SC review	2 weeks
Address SC issues: Version 4	2 weeks
NIDA approval: Version 4	2 weeks
Total protocol development time	**48 weeks**