

CTN-POL-012	NIDA PROTOCOL REVIEW BOARD	Date Approved: Sep 00
Approved by: SC	Date Revised: Revised by:	Page 1 of 1

A. Introduction

In order for a study to be initiated in the CCTN, the protocol must be approved by the NIDA CCTN Protocol Review Board (PRB). This document outlines the policy related to the NIDA PRB. The purpose of this policy is to provide guidelines for the establishment, authority, function, and responsibility of the Board.

B. Establishment

The NIDA PRB is an expert Board appointed and chaired by the NIDA CCTN Director or his/her designee. The Board is comprised of experts from the government, academia and industry who are not associated with the CCTN.

C. Authority and Function

The Board is authorized by the Director of NIDA to review the final draft of the protocol submitted by the CCTN Lead Investigator for methodology (both scientific and statistical), feasibility, safety, regulatory, and ethical issues relative to NIDA's sponsorship. All safety, regulatory and ethical concerns must have been addressed to the satisfaction of the PRB before a study opens to accrual.

D. Responsibility

The Board members will meet in person 3 to 4 times annually or via conference calls if additional reviews are necessary. The responsibilities of the Protocol Review Board are:

1. Review protocols and provide scientific advice and recommendations to the NIDA/CCTN Office;
2. Evaluate the safety, regulatory, and ethical issues involving human subjects;
3. Provide an overall evaluation of the feasibility of protocol implementation in the community-based-treatment programs;
4. Assess the relevance of the study in the treatment for drug addiction.