

CTN-POL-017	CTN PROTOCOL AMENDMENT	Date Approved: Jan 01
Approved by: SC	Date Revised: Revised by:	Page 1 of 1

Introduction: Research protocols to be studied in the CTN are generated from a Lead Investigator and reviewed by the Steering Committee. These protocols are in turn approved by NIDA s Protocol Review Board and submitted to local IRB s for approval prior to implementation at the CTP. This document outlines the policy for protocol amendment, once approved by NIDA s Protocol Review Board.

Policy:

- Protocols are considered final once the LI receives the NIDA Protocol Review Board approval letter
- Once approved, if the LI needs to change the protocol, then he/she must submit the request in writing to the Operations Committee (OC)
- The OC will discuss the changes on its next scheduled conference call and notify the recommendations to the LI. The OC will defer the discussion to the Steering Committee when necessary.

Protocol Amendment Request:

- The LI must submit a letter to the OC requesting the change. The letter should include a rationale for the amendment and address the impact on the following:
 - Data Management
 - Training
 - Regulatory (such as IRB process)
 - Budget
- The OC Chair will submit recommendations to the LI after reviewing request