CTN-POL-015	**Regulatory Affairs Policy**	Date Approved: 20 Sep 00
Approved by: SC	Date Revised: Revised by:	Page 1 of 1

A. Introduction/Purpose

The NIDA Clinical Trials Network (CTN) is a recognized cooperative protocol research program (CPRP) involving community based treatment programs, researchers and NIDA.

The Steering Committee of the CTN created the Regulatory Affairs Subcommittee (RAS) as an advisory group to document the regulatory compliance and efforts to protect the right and welfare of volunteers involved in clinical and other studies conducted by the CTN. The RAS will oversee compliance with all laws, guidelines and policies; including, but not limited to, Title 21 CFR 50, 56 & 312; 42 CFR 2a, and 45 CRF 46. The Steering Committee has final authority for approval or disapproval of recommendations of the RAS.

B. Responsibilities of the Regulatory Affairs Subcommittee

1. The RAS will assist the Lead Investigators and the Steering Committee ensure compliance with all institutional, local, state, and federal government regulatory laws, guidelines & policies; including, but not limited to:
   - Obtaining (and maintaining) Single, Multiple or Cooperative Project Assurances with the Office for Human Research Protections.
   - Obtaining Confidentiality Certificate(s) for each protocol.
   - Reporting Serious Adverse Events to appropriate parties.
   - Filing Investigational New Drug (IND) applications with FDA when necessary.
   - Registering with DEA when necessary.
   - Reviewing and maintain updated information on the membership of all Node Institutional Review Boards (IRB) participating in review of CTN protocols. Provide the CTN office IRB memberships and annual reports.
   - Documenting that each CTN protocol, consent form and other study materials – such as advertisements, brochures, and etc.- have been approved by the responsible IRB prior to subject enrollment. Document IRB approval for the amendments and/or revisions of such materials.
   - Following up with participating IRBs to encourage timely reviews
2. Coordinate activities with the Quality Assurance Subcommittee, other subcommittees, teams, Nodes, etc., as appropriate.
3. Review CTN protocols and consent forms to confirm their completeness and provide feedback to the protocol development team.
4. Assist Node and CTP staff in maintaining adequate records.
5. Report regularly to the Steering Committee and, as needed, to all other relevant parties.