A. Introduction/Purpose

The multi-site, multi-protocol nature of NIDA's National Drug Abuse Treatment Clinical Trials Network (CTN) presents a challenge regarding assurance of quality and consistency in protocol conduct. This policy has been developed to ensure the quality and integrity of clinical trials, the protection of human subjects and to advance the collaboration between treatment and research staff. These activities specifically relate to the performance of the CTN studies.

This policy emphasizes continuous quality improvement from design of the protocol through publication of the results. It provides guidelines for ensuring data accuracy, compliance with protocols, and regulatory/human safety requirements. The actual processes used to implement this policy may differ by protocol and individual node.

B. Objectives

The quality assurance policy has these objectives:

- Ensure quality assurance procedures are included in protocol design, development, and implementation
- Ensure accurate data collection
- Ensure compliance with protocol
- Ensure compliance with standards for protection of human subjects
- Encourage the culture of continuous quality improvement

C. Responsibilities of the Quality Assurance Subcommittee (QAS)

- Develop, recommend for approval and implement quality assurance policies and procedures for protocols conducted in the CTN
- Collaborate with other sub-committees e.g., training, data management, regulatory, to ensure that QA issues are addressed and necessary plans are developed
- Collaborate with the protocol development teams to ensure that relevant QA issues are addressed in all protocols
- Review all protocol QA plans for completeness and recommend for approval
- Monitor the implementation and conduct of all protocols for compliance with the standards for protection of human subjects
- Serve as an advisory resource for QA issues
- Review QA activities reports generated by the nodes and will support or recommend plans of action as indicated
- Report regularly to the Steering Committee

D. Assumptions

- The Lead Investigator (LI) has the ultimate responsibility to ensure that all necessary protocol specific plans are developed and in place prior to protocol implementation

- The node Principal Investigator (PI) has the ultimate responsibility to ensure adherence to all necessary plans for their node.
- NIDA provides periodic independent monitoring of the CTN QA processes
- NIDA provides final approval for a trial to begin (overall and at each node) with the assistance of Steering Committee subcommittees

E. References

- Cooper, G.R., *"The Importance of Quality Control in the Multiple Risk Factor Intervention Trial"*, Controlled Clinical Trials, Vol. 7, No. 3 (Supplement), Sep 1986
- Knatterud, G.L, et.al., *"Guidelines for Quality Assurance in Multicenter Trials: A Position Paper"*, Controlled Clinical Trials, Vol. 19, 1998, pp 477-493

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