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 data and consistency in data collection. This policy has been developed to ensure the quality and consistency of clinical trial data, the confidentiality of data and to advance the collaboration between treatment and research staff. These activities specifically relate to the performance of the CTN studies.

This policy emphasizes quality and consistency from design of the protocol through publication of the results. It provides guidelines for ensuring consistent data collection, accurate data transfer, and compliance with the International Conference on Harmonization guidance policies. The actual processes used to implement this policy may differ by protocol and individual node.

The Data Management and Analysis subcommittee provides advice and assistance to the CTN Steering Committee on research design, study analysis, and the information systems (data collection instruments and systems) used to gather, analyze, and report data from CTN studies. The subcommittee also serves an advisory role to the CTN Steering Committee on the management of data in CTN research projects.

B. Objectives (of the Policy)

The Data Management and Analysis Policy has these objectives:

- Assure the quality of data management activities.
- Ensure accurate and consistent data collection
- Ensure data management and analysis procedures are considered in protocol design, development, and implementation
- Facilitate the exchange of information on matters related to the design and operation of clinical trial data acquisition systems
- Facilitate the discussion of issues related to statistical analyses and reporting of results

C. Responsibilities of the Data Management and Analysis Subcommittee (DMAS)

- Develop, recommend for approval and implement data collection and processing policies and procedures for protocols
- Develop and maintain data standards to ensure comparability among research projects
- Develop and maintain recommendations for Table Templates for inclusion in Study Reports
- Collaborate with other sub-committees e.g., training, quality assurance, regulatory, to ensure that Data issues are addressed and necessary plans are developed
- Collaborate with the protocol development teams to ensure that relevant Data and Statistical issues are addressed in all protocols
- Review all protocol Data Management and Data System QA plans for completeness and recommend for approval

- Serve as an advisory resource for issues related to protocol design, data management and statistical analysis
- Report regularly to the Steering Committee

D. <u>Assumptions</u>

- 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.
- The CTN will develop and maintain a Forms Library (catalog of forms) for use in protocols
- The CTN will develop and maintain a Data Dictionary for each form contained in the Library
- A standard set of table templates can be developed for use in reporting results
- Familiarity with current standards for reporting such as International Committee on Harmonization Good Clinical Practices guidelines will be maintained

E. <u>Glossary</u>

Case Report Form: An instrument for the collection of data. May also be referred to as a data collection instrument. Abbreviated as CRF.

Data Dictionary: An instrument which specifies the variable specifications for one Case Report Form, along with associated logic checks.

Forms Library: A catalog of Case Report Forms which have been used in prior studies.

Global Data Dictionary: A collection of Data Dictionaries that should be consulted when developing a form specific data dictionary.

Information System: The data acquisition (includes CRFs), management, storage, and reporting systems.