

Attachment 16

PATH Study Procedures for Keeping Data Confidential



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Westat's Procedures for Keeping Data Confidential

Following is a description of the procedures Westat will take to keep confidential the study data collected from the PATH study respondents.

- Study data will be identified and retrieved by a study number only. Investigators will not have access to Personally Identifiable Information such as social security number (SSN), name, or address.
- Personally Identifiable Information (name, address, email address, and telephone numbers, etc.) will be stored in a secure database environment that is compliant with FISMA Moderate security guidelines.
- Hard-copy data forms will be identified only by a study identification number and will be stored in locked files at the contractor's facilities.
- All computerized data will be maintained in a manner that is consistent with FISMA Moderate security controls and guidelines identified in NIST Special Publication 800-53.
- All systems and databases handling or storing PII and/or PHI will be reviewed for FISMA compliance by the NIDA Chief Information Officer (CIO) and Information Systems Security Officer (ISSO), and will not be operated in production mode until granted an Authority To Operate (ATO) by NIDA.
- No reports or data files will contain personal identifiers.
- All contract staff working on the study will be required to sign a statement pledging to keep all study data confidential.
- All contract staff members are required to undergo background screening commensurate with their role on the project and their access to study data.
- All contract staff are required to complete NIH Computer Security Awareness Training as well as Privacy Awareness Training.
- Access to study data will be limited to the staff working on the study.
- When the study is complete or until the data is no longer required for research, the data will be stored or destroyed so that only necessary and useful records are retained in the files of NIH offices and laboratories for as long as required and reasonable and that records with lasting historical, legal or scientific value are preserved.