

Data Security

Adequate administrative, operational, and technical security controls will be implemented to prevent unauthorized access to or disclosure of any personally identifiable information (PII) that will be accessed by the contractor. Electronic transfers of PII via Internet or portable media will utilize FIPS 140-2 compliant encryption. The final de-identified dataset with data collected on all participants will be delivered to CDC/ATSDR, UNM, and NNDOH using excel files with encrypted, password coded spreadsheets through a password protected data sharing facility

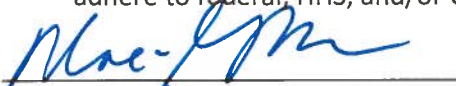
For scheduling and medical record access, lead NBCS research team members will need linkage information for individual participants and entry of data. They will be asked to destroy that linked information on completion of the interview, and no data collected in the field will be entered into the electronic data files by any identifier other than participant number. All members of the NBCS research team will be required to complete UNM (or NAIHS) privacy protection, confidentiality, and health information security trainings, as well as Collaborative Institutional Training Initiative (CITI) training for research with human participants.

The Privacy Act of 1974 applies under System of Records Notice 09-19-0001 Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances. Adequate administrative, operational, and technical security controls will be implemented to prevent unauthorized access to or disclosure of any personally identifiable information (PII).

Security Plan

In order to properly safeguard non-public information, NNDOH shall ensure stewardship of the study data throughout all phases of the NBCS, and follow the systems and methods designed and maintained by the PI and staff at UNM- CEHP.

1. NNDOH staff shall be trained in and follow the IRB and OMB approved, detailed project plan that addresses data collection methods, measures to protect participant privacy, security of data, and chain of custody.
2. NNDOH staff shall follow approved methods that will be used for data collection (paper and electronic questionnaires).
3. NNDOH staff shall follow UNM-CEHP protocols to train the interviewers and develop competency.
4. NNDOH staff shall follow all measures to keep study data and participant information confidential and secure.
5. NNDOH shall assist UNM-CEHP staff to ensure that all data are entered into UNM-HSC-CEHP REDCap data management and software system.
6. NNDOH will not use personally-owned hardware or software to collect, store, process, or transmit data under the contract: they can only use resources approved under the cooperative agreement.
7. Any laptops purchased under the CDC contract for the study are exclusively for NBCS official use, and must meet U.S. Government configuration standards. NNDOH will use these laptops but will enter data through direct connection to UNM servers or through offline encrypted media provided by UNM.
8. NNDOH shall follow UNM-CEHP's plan for disposition of any paper documents and questionnaires used in emergency situations, and shall destroy any contact information required for scheduling of interviews.
9. Changes in this plan will be communicated to ATSDR before implementation to ensure NNDOH continues to adhere to federal, HHS, and/or CDC IT security policies.



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Data and IT Security Plan Background Information

Electronic reporting will be used to collect all questionnaire data for this program. This study will use the RedCap™ CAPI development tool. The University of New Mexico has secured a license for RedCap™ software, and UNM will develop RedCap™ based CAPI. RedCap™ is a secure application for building and managing surveys and databases. RedCap™ is currently utilized by other Centers for Disease Control and Prevention programs such as the Division of Global HIV/AIDS. Data collection using RedCap™ will occur using the following:

- a. Direct on-line connection to the RedCap™ system: This online connection occurs through a secure virtual private network (VPN) tunnel that disables any other network connections on machines. Data transfer when an internet connection is available occurs by utilization of the encrypted transfer protocol inside the RedCap™ system, again inside the VPN secure tunnel. The system generates an email notification of an available file transfer, followed by a second notification of a password necessary to open that encrypted file package.
- b. Off-line collection RedCap™ system process: This offline collection generates an encrypted file stored in a truecrypt basket on the machine. That encrypted file basket is closed on removal of the drive. UNM staff performs regular QA of new data on a weekly basis, and will conduct field review and follow-up with NNDOH staff monthly.

The RedCap™ CAPI will be deployed on laptop computers to collect data in designated clinics and field sites. Trained CHERs will administer surveys in the field and record responses in RedCap™. Data collected via RedCap™ can be aggregated, reported and exported using a variety of formats including XML and Microsoft Excel. CHERs will receive extensive training on data entry and laptop security and will follow all guidelines outlined in the approved RedCap Data & Security Plan.

For scheduling and medical record access, lead research team members will need linkage information for individual participants and entry of data. They will be asked to destroy that linked information on completion of the interview, and no data collected in the field will be entered into the electronic data files by any identifier other than participant number. All members of the research team will be required to complete UNM (or NAIHS) privacy protection, confidentiality, and health information security trainings, as well as Collaborative Institutional Training Initiative (CITI) training for research with human participants.

Dr. Lewis and the lead research team (UNM Project Coordinator/Database Manager, Navajo Nation Department of Health Project Coordinator, and the Clinical Liaisons at each of the five Navajo Area Indian Health Service / PL-638 health facilities) will be the only study personnel with access to information linking participants' names to their participant numbers. IIF will be used for the purpose of 1) follow-up of participants for home and prenatal care visits at the Indian Health Service clinics and healthcare facilities contracted with Navajo Nation Department of Health through Public Law 93-638 (PL-638) providers and 2) recording and clarifying information that has been provided by the CHERs for data quality and control purposes.

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Field research staff will have access to enter data based on participant study number; the database manager will have full privileges; statisticians and modelers will have authorization to read and export data; while team members with no data entry or manipulation responsibilities will have read-only privileges. The lead research team members who provide Quality Assurance/Quality Control (QA/QC) for the data will have time-limited access to edit specific datasets until QA is completed. Reports to team members with no responsibilities for data entry, QA, or analysis will be exported through requests to the database manager to ensure adequate metadata accompanies the report.