

Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation:

Circumstances of Change Request for OMB # 0923-0046

This is a nonmaterial/non-substantive change request for OMB protocol #0923-0046 which in February 2013 received a three-year approval through February 29, 2016. OMB approval was granted for data collection for a research cooperative agreement program involving University of New Mexico (UNM).

We are requesting to change from survey instruments developed using the Rapid Data Collector (RDC) to Research Electronic Data Capture (RedCap™) CAPI survey instruments. UNM has secured a license for RedCap™ software, and UNM will develop RedCap™ based CAPI. The RedCap™ CAPI will be deployed on laptop computers to collect data in designated clinics and field sites. The NCEH/ATSDR Information Systems Security Officer (ISSO) has approved the Data Privacy & Security Plan to ensure measures are in place to protect participant data while using RedCap™ software.

UNM is no longer able to use the RDC as their CAPI tool for the survey interviews. The RDC 1.37 was migrated to a new version (RDC 2.0). UNM has had several issues with RDC 2.0 such as 1) inability to load the program and get it operational on laptop computers with certain operating systems 2) extended amount of time to save survey responses, reload surveys, and access questions to the point from which the survey resumes 3) error messages for some questions that incorporate skip logic. These issues have caused significant delays in program implementation and have extended staff time and resources. In addition, the RDC 2.0 offline program seems to require a laptop with at least 12 GB RAM and a Windows 7™ operating system. These high end requirements are out of the scope of program budgets and technical support. As a result, the RDC 2.0 offline program is not feasible for field surveys at this time.

As part of the OMB approval for the study, UNM was approved to use a scheduling tool to create prompts for research members to schedule individual participants in a timely manner. The scheduling tool that is being used is RedCap™; therefore, this is a nonmaterial/non-substantive change request. Also, RedCap™ is currently being used by other CDC programs to collect data.