

Response to OMB Queries: August 26, 2013

WHAM Study – RTI International in partnership with Lyon-Martin Health Services

Request for SORN for WHAM Study:

In Section 10 of our Supporting Statement A we had included a statement indicating that would provide a System of Record Number for this project. However, upon closer review, we determined that our project does not meet all three criteria for a required SORN since records in the system cannot be retrieved by name or other personal identifier. This statement was inadvertently included in our final application. As described in 10B, we have established a number of safeguards to assure participant privacy that have been reviewed and approved by the RTI IRB. These include assignment of a unique study identification number that will be used for all data collection activities; staff training; and data security procedures for data collection and management. Though we will be recruiting study participants from a clinic population (alongside community-based recruitment), all data collection will remain specific to the study and will not be integrated into patient visits and clinic records.

Data Security to Minimize Loss of Privacy.

It is RTI's policy that the fewer the number of individuals handling sensitive information, the greater the protection. Research activities will be carried out by the Principal Investigator and Project Coordinator with involvement by other RTI scientific advisors on the project. Project files and databases will be available only to research personnel through the authorization of the Principal Investigator. Staff who will have access to data or interact with participants must sign confidentiality agreements and will be informed of their responsibility to maintain confidentiality once they have left the study or the study has ended. Staff will be trained on the policies and procedures for data management and transmission, and will also receive instructions on how to report any violations of those policies and procedures.

All consent and data forms will be kept in locked files in the San Francisco RTI offices. All paper copy interview data will be hand carried to the SF RTI office where it will be stored in a locked filing cabinet in a secure location. Consent forms, which will include participant names, will be kept in a separate locked file cabinet from the completed data collection forms. No personal identifiers (other than date of birth) will be included on data collection forms. Forms will be coded only with the unique numerical identifier given to each participant. Computer records will be password-protected and stored on RTI encrypted computers to prohibit illicit access.