## **Non-Research Determination**

## National Surveillance for Severe Adverse Events Associated with Treatment of Latent Tuberculosis Infection Extension Request Current OMB No. 0920-0773 Expiring 01/17/2018

CDC is requesting extension of the currently approved National Surveillance for Severe Adverse Events Associated with Treatment of Latent Tuberculosis Infection (NSSAE) OMB No. 0920-0773 data collection form for the national surveillance system.

We have determined that the information collection is public health surveillance rather than research involving human subjects, thus IRB review and approval are not required. The national tuberculosis surveillance system has been conducted and maintained by the U.S. Public Health Service through the cooperation of the states since 1953. CDC conducts and maintains the system pursuant to the provisions of Section 301(a) of the Public Health Service Act (42 U.S.C. 241) and Section 306 of the Public Health Service Act (42 U.S.C. 241 (a)]. Data are protected by an assurance of confidentiality under Section 308(d) of the Public Health Service Act [42 U.S.C. 242m(d)], which prohibits disclosure of any information that could be used to directly or indirectly identify patients.

Date:  $\frac{5/3}{7}$ 

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