

United States Food and Drug Administration

Donor Risk Assessment Questionnaire for the Food and Drug Administration (FDA)/National Heart, Lung, and Blood Institute (NHLBI)-Sponsored Transfusion-Transmissible Infections Monitoring System (TTIMS)—Risk Factor Elicitation (RFE)

OMB Control No. 0910-0841

JUSTIFICATION MEMORANDUM FOR 83-C CHANGE REQUEST

The Food and Drug Administration (FDA or we) is submitting this nonmaterial/non-substantive change request (83-C) to obtain Office of Management and Budget (OMB) approval of a modification to the study approved under control number 0910-0841. The current OMB approval allows FDA to interview blood donors to collect risk factor information associated with testing positive for a transfusion-transmissible infection (TTI). This study currently monitors and evaluates risk factors among HIV-positive donors and recently HCV or HBV infected donors as well as controls. To ensure adequate data quality, we would like to change the characteristics of the universe of respondents by adding donors who test positive for syphilis and including additional donors testing positive or reactive for other tests for Hepatitis B.

The proposed modification does not impact the current approved burden estimate. We estimate no change to the questionnaire or in the time needed to complete an interview. With the lower than anticipated rates of infections in donors, there exists the capacity to increase the scope of the monitoring program without increasing the total respondent burden hours. Including all study sites, we expect no more than 250 of these syphilis and additional control interviews per year (83 active syphilis cases and 167 controls). Thus, the total number of annual interviews is expected to remain under the existing OMB approval of 600 per year. At 0.5 hour per interview, the total burden hours remain unchanged at 300 hours.

FDA will use these scientific data collected through such interview-based risk factor elicitation of blood donors to monitor and help ensure the safety of the U.S. blood supply.