FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF RAPID RESPONSE SURVEYS (0910-0500)

FDA uses the Rapid Response Surveys to further develop tools and science necessary to better understand where vulnerabilities are and the most effective ways to minimize them, as well as to intervene and respond once a problem occurs.

TITLE OF INFORMATION COLLECTION: MERS-CoV rapid survey of blood donors

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **What is the problem to be investigated:**

Blood safety and blood availability are among two of the more important public health responsibilities that FDA shares with other agencies and blood collecting organizations. FDA's ability to react quickly and appropriately with effective public health policies depends upon rapid and accurate assessment of the risk of transfusion transmitted disease and the impact of any change in blood donor policy on the availability of blood. In situations of rapidly emerging infectious diseases (EID), it is vital that potential exposures of blood donors to EIDs be rapidly surveyed. FDA seeks to develop in collaboration with the blood collecting organizations a system to rapidly survey and analyze the responses of past and potential future blood donors from donor lists maintained by blood collecting organizations using electronic means (e.g. email, web surveys).

At present, an EID in the Middle East, specifically, in Saudi Arabia, Qatar, United Arab Emirates, and Jordan known as Middle East Respiratory Syndrome-Coronavirus (MERS-CoV) has an unknown potential to spread to the U.S. through blood donors who have recently traveled to the these countries. FDA is contracting with AABB (formerly the American Association of Blood Banks) and NORC (National Opinion Research Center) to survey, through blood collecting organizations, former blood donors on their travel to countries where MERS-CoV is emerging, to anonymize the responses, to collate, and to share the results with FDA. This survey and data sharing by multiple blood collecting organizations represents the development of a new capacity which may reveal unforeseen challenges. Consequently, to maximize the likelihood of getting meaningful results we plan to do a pilot survey first with 100 respondents per blood collecting organization followed by a preliminary analysis that will provide feedback for the scaled up survey of at least 1,000 respondents per blood collecting organization. The blood collecting organizations are concurrently seeking approvals for the survey with their institutional review boards (IRBs). The survey data will play an important role in reducing the uncertainty of risk estimates of MERS-CoV or in future surveys, other blood-borne EIDs. Accurate risk estimates for MERS-CoV exposures will assist in the formulation of policy and risk communications that will increase the safety of the blood supply while minimizing the impact on blood availability. The result will be enhanced protection of public health.

2. **Please describe the method to obtain the convenience sample:**

Each of five Blood Collection Organizations (BCOs) will construct a sample frame from their organizational list of blood donors. The sample frame will include only individuals who are at least 18 years of age, are allogeneic donors, and have donated blood at least once in the last year. In addition, the sample frames will be limited to those individuals who have provided contact information including either email address or cell phone

number. Each BCO will select a random sample of donors from its sample frame. The selected donors will be contacted using either email or a text message and asked to complete a short web-survey. Response is entirely voluntary and donors will be asked for consent to participate.

Each selected donor will be provided with a PIN to use in responding to the survey in order to ensure that those who respond are the blood donors selected and that each donor only responds once. This PIN contains no identifying information and only the BCO retains the cross-walk between the PIN and the sample frame of blood donors. No identifying information is retained on the subsequent data file that the BCO submits for analysis.

Response is entirely voluntary. Based on the BCOs previous experience with similar surveys, the expected response rate for "repeat" donors is approximately 20%. Therefore the selected sample will be 5 to 10 times the size of the respondent sample size required. The pilot study will provide information to further refine the estimates of response rates over both repeat and first time donors for the Scale-Up. The goal of the pilot is to obtain 100 responses from each BCO for a total of 500 responses, and the Scale-Up will result in a total of at least 5,000 responses.

Each BCO will compile the respondent data and will add to it demographic information of age, gender and geographic location (by zip code or state) as well as information on the type of blood donation and whether or not they are repeat donors. These data will be aggregated by NORC over all BCOs to ensure confidentiality (e.g., aggregating year of birth into categories of ages and state/zip code into USPHS regions). No identifying information will be contained on the final data file sent to the FDA.

3. **Are there any deviations to the described methods, procedures, and uses of data contained in the Rapid Response Survey 2011 Justification Statement:**
   YES / NO (if no skip to #5)

   NO

4. **If yes, please describe:**

5. **Burden Chart and Description:**

Based on testing of the brief questionnaire and extensive corporate experience with web-based surveys of this type, it is anticipated that respondents will complete the instrument in five or less minutes. This timing is conservative assuming that respondents will answer questions in a way that requires they answer all items rather than being screened out due to a lack of travel to countries of interest. The burden table below provides three estimates. The first row provides information on the pilot, which will include 500 respondents, 100 from each participating organization. The second row includes the scale up, with 5,000 total respondents. The third row includes the total burden for both groups. Given the survey will take five minutes or less, we use 0.08% of an hour in our calculations.

BURDEN HOUR COMPUTATION

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Rapid Response Survey - Pilot	500	.0833 (5 minutes)	41.67
Rapid Response Survey – Scale-Up	5,000	.0833 (5 minutes)	416.67
Total Rapid Response Survey	5,500	.0833 (5 minutes)	458.33

Attach Questions

Attached are seven questions of which most respondents will only answer four questions. The questions address travel to specific Middle Eastern countries, length of time spent in specific countries, time since return, contact with individuals who have recently traveled to specific countries, and the respondent family's history of recent severe respiratory illness.

REQUESTED APPROVAL DATE: 15 March 2014

NAME OF PRA ANALYST & PROGRAM CONTACT:
FDA: Ila S. Mizrachi
CBER: Stephen Ripley

FDA CENTER: Center for Biologics and Evaluation and Research