

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: Hepatitis E virus-exposure 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).

Hepatitis E virus (HEV) is an EID that causes 20 million cases worldwide and is estimated to cause 56,600 Hepatitis E related deaths per year. HEV prevalence in the U.S. general population is low, but HEV represents a threat because of its prevalence in U.S. swine herds and potential exposures to blood donors who travel to developing parts of the world. Transfusion-transmitted HEV is a problem in the U.S. because some blood donors who have HEV can be asymptomatic and there are no approved screening tests for HEV contaminated blood at present. The survey seeks to determine the number of blood donors who engage in activities that lead to potential HEV exposures. FDA is contracting with AABB (formerly American Association of Blood Banks) and National Opinion Research Center (NORC) to survey, through blood collecting organizations (BCOs), former blood donors on their potential exposure to domestic and foreign sources of HEV, to anonymize the responses, to collate, and to share the results with FDA. This survey and data sharing by multiple BCOs represents the refinement of a new capacity to get exposure information of a specific population, rather than estimating blood donor exposure data based on general population behavior. We are seeking a statistically representative sample from 1,000 respondents per BCO. The BCOs 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 for transfusion transmitted HEV or in future surveys, for other fecal-oral route Hepatitis virus infections. Accurate risk estimates for HEV 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 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 by email and asked to complete a short web-survey on the NORC web site. Response to the survey is entirely voluntary and donors will be asked for consent to participate. There will be no incentive offered to participate.

No identifying information is retained by NORC with the subsequent data file used for analysis.

Based on the previous experience with a similar survey, the expected response rate for “repeat” donors is approximately 12%. Therefore the selected sample will be 8 to 10 times the size of the respondent sample size required. The goal of the pilot is to obtain 1,000 responses from each BCO for a total of at least 5,000 responses.

NORC will compile the respondent data and 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 U.S. Public Health Service regions). No identifying information will be retained by NORC or be contained in the final data file sent to the BCOs or to 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:

Candidate respondents will receive an email message from their BCO directing them to the NORC website. At the NORC website, candidate respondents will read the introduction to the survey in the consent form. After consenting to the survey, respondents will be requested to answer as few as 4 questions or as many as 7 questions depending on their environment and/or behavior. The entire process will take about 5 minutes.

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Rapid Response Survey	5000	.08333 (5 min.)	416.67

6. Attach Questions

REQUESTED APPROVAL DATE: 15 October 2015

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