

request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

**ADDRESSES:** All documents relating to this determination are available for inspection between the hours of 8:30 a.m. and 4:30 p.m., Monday through Friday, at the following offices: Alabama Department of Environmental Management, Drinking Water Branch, 1400 Coliseum Boulevard, Montgomery, Alabama 36130; and the U.S. Environmental Protection Agency, Region 4, Safe Drinking Water Branch, 61 Forsyth Street, SW., Atlanta, Georgia 30303.

**FOR FURTHER INFORMATION CONTACT:** Tom Plouff, P.E., EPA Region 4, Safe Drinking Water Branch, at the address given above, by telephone at (404) 562-9476, or at [plouff.tom@epa.gov](mailto:plouff.tom@epa.gov).

**Authority:** Section 1413 of the Safe Drinking Water Act, as amended (1996), and 40 CFR part 142.

Dated: April 20, 2010.

**J. Scott Gordon,**

*Acting Regional Administrator, Region 4.*

[FR Doc. 2010-10173 Filed 4-30-10; 8:45 am]

**BILLING CODE 6560-50-P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; Comment Request; Investigating the Causes of Post Donation Information (PDI): Errors in the Donor Screening Process

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 23, 2010, Volume 75, No. 35, pages 8080-8081 and allowed 60 days for public comment. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a current valid OMB control number.

**Proposed Collection: Title:** Investigating the causes of post donation information (PDI): Errors in the donor screening process. **Type of Information Collection Request:** NEW. **Need and Use of Information Collection:** Blood centers are required to use a health history screening questionnaire to obtain eligibility information for the protection of the donor and recipient prior to blood donation. However, the health history process is known to be error-prone and the reasons for those errors are largely unknown and untested. Donors often fail to report a risk that would have resulted in deferral. This deferral risk may be disclosed at a subsequent donation and is classified as Post Donation Information (PDI). While this deferral risk may be at the next donation event, many examples of PDI are not disclosed nor discovered until several intervening donation events have occurred. The reasons why donors fail to disclose a deferrable history at the time of one donation but subsequently disclose this information at a later time are unidentified. This protocol is designed to ascertain why PDI error events occur. It will be the first study of any kind to address the issue of PDI errors in any systematic fashion. By conducting interviews with donors involved in PDI errors, we will gain important qualitative knowledge about this problem. Information gathered from these interviews will not only elucidate the issue of PDI but will provide insight into donor understanding of the screening process and their feelings about the process and blood donation in general.

The main objectives of the study are:

1. To explore reasons behind errors in the donor screening process when donors initially fail to disclose an accurate and complete health history.
2. To explore PDI donors' knowledge, attitudes, behaviors and beliefs (KABB) about the health history questionnaire and their experience with the screening process and the center.
3. To compare KABB in PDI donors to deferred (but not PDI) donors and accepted donors.

The study sample will consist of three groups:

1. Donors with a PDI: all identified donors of interest with an FDA reportable donor suitability error classified as PDI at the REDS-II centers.
2. Deferred donors: appropriately deferred (but not PDI deferred donors) at the REDS-II centers.
3. Accepted Donors: appropriately accepted for donation at the REDS-II centers.

Telephone interviews will be conducted with consented donors to

collect information regarding their knowledge, attitudes, behaviors and beliefs about the donor health history process. Even though the interviews with the donors will be individual, we would like to form groups of similar PDI and deferred donors for analysis purposes.

The five groups of interest include PDI occurrences or deferrals that are due to:

- Travel (malaria, vCJD).
- Medical (history of diseases including jaundice/hepatitis, surgery and medications needed to treat disease including Tegison, Proscar and Accutane).
- Blood/Disease Exposure—(tattoo, piercings, accidental needle stick).
- High Risk Behavior—Sexual (MSM, sex with IV drug user or test-positive individual).
- High Risk Behavior—Non-Sexual (IV drug use, non-sexual exposure to Hepatitis C or Hepatitis B).

All interviews will be digitally-recorded and the recordings uploaded onto computers as dss files; these files will be transcribed and then coupled to the interviewer notes to form an analytic package for the data analysts. Once the interview is conducted successfully, each study donor will be mailed a check of \$25 as an incentive for participating in the study.

The cognitive testing of the interview guide will be conducted at the Hoxworth Blood Center. For this purpose, the blood center staff will identify 2 PDI and 2 deferred donors from the five broad categories of interest. They will also contact 2 accepted donors for study consent and interview. These donors will be approached and consented by following the same procedures that will be used for the actual study.

The data from the semi-structured interviews will be analyzed in two ways. The close-ended responses will be analyzed quantitatively. This will likely take the form of 3-way cross-tabulations of frequency distributions in responses to key questions. The open-ended responses will be analyzed as qualitative data. All analytic steps and assumptions that led up to the conclusions, including competing interpretations of the data, will be fully discussed in the final report.

**Frequency of Response:** Once.  
**Affected Public:** Individuals. **Type of Respondents:** Adult blood donors. The annual reporting burden is as follows: **Estimated Number of Respondents:** 408; **Estimated Number of Responses per Respondent:** 1; **Average Burden of Hours per Response:** 0.08 for the initial phone call and 0.5 for responding to the

actual interview; and *Estimated Total Annual Burden Hours Requested*: 83.64. The annualized cost to respondents is estimated at: \$1505.52

(based on \$18 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

**Table 1: Estimate of Requested Burden Hours and Dollar Value of Burden Hours**

TABLE A.12-1 ESTIMATES OF HOUR BURDEN

Type of respondents	No. of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Donors initially contacted .....	408	1	.08	32.6
PDI Donors .....	*60	1	0.5	30
Deferred Donors .....	*30	1	0.5	15
Accepted Donors .....	*12	1	0.5	6
Total .....	408	.....	.....	83.64

\*These respondents are a subgroup of total 408 donors who will be initially contacted to participate in the study.

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*Direct Comments to OMB:* Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA\_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. George Nemo, Project Officer, NHLBI, Two Rockledge Center, Suite 361, 6700 Rockledge Drive, Bethesda, MD 20892, or call non-toll-free number 301-435-0075, or e-mail your request, including your address to *nemog@nih.gov*.

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received *within 30 days* of the date of this publication.

Dated: April 26, 2010.  
**George Nemo,**  
*Project Officer, NHLBI, National Institutes of Health.*  
 [FR Doc. 2010-10283 Filed 4-30-10; 8:45 am]  
**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Agency for Healthcare Research and Quality**

**Agency Information Collection Activities: Proposed Collection; Comment Request**

**AGENCY:** Agency for Healthcare Research and Quality, HHS.  
**ACTION:** Notice.

**SUMMARY:** This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Standardizing Antibiotic Use in Long-Term Care Settings SAUL) Study." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3520, AHRQ invites the public to comment on this proposed information collection.

**DATES:** Comments on this notice must be received by July 2, 2010.

**ADDRESSES:** Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by e-mail at *doris.lefkowitz@AHRQ.hhs.gov*.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

**FOR FURTHER INFORMATION CONTACT:** Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by e-mail at *doris.lefkowitz@AHRQ.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

**Proposed Project**

*Standardizing Antibiotic Use in Long-Term Care Settings (SAUL)*

Study Inappropriate antibiotic prescribing practices by primary care clinicians caring for residents in long-term care (LTC) communities is becoming a major public health concern as it is a risk factor for morbidity and mortality among LTC residents. Antibiotics are among the most commonly prescribed pharmaceuticals in LTC settings, yet reports indicate that a high proportion of antibiotic prescriptions are inappropriate. The adverse consequences of inappropriate prescribing practices are serious and include drug reactions/interactions, secondary complications, and the emergence of multi-drug resistant organisms.

In an effort to reduce antibiotic overprescribing, Loeb and colleagues developed minimum criteria for the initiation of antibiotics in LTC setting (Loeb, M., *et al.* 2001). The criteria have been tested in several studies, but their implementation and tests of validity have been limited. In particular, though Loeb and colleagues developed distinct minimum criteria for several types of infection (skin and soft-tissue, respiratory, urinary tract, and unexplained fever), a rigorous evaluation has been conducted only for urinary tract infections.

Twelve nursing homes (NH) will participate in this project; six NHs will be recruited to serve as treatment sites and six to serve as control sites. Once a nursing home community has been selected and randomly assigned to the treatment or control group, a facility recruitment letter will be sent to the facility Administrator. The letter will include a description of the study and inform the Administrator that the