DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–23–00]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Projects

1. Telephone Survey Measuring HIV/STD Risk Behavior Using Standard Methodology—New—The Behavioral Surveillance Working Group, coordinated by the National Center for HIV, STD and Tuberculosis Prevention (NCHSTP). Proposes to conduct testing of a set of survey questions intended to obtain measures of risk behaviors for Human Immunodeficiency Virus (HIV) and Sexually Transmitted Diseases (STDs). Knowledge about the level of HIV risk behaviors in populations is essential for effective HIV prevention programs. Currently, survey-based assessment of these behaviors depends on a range of survey questions that differ across survey, and that are difficult to compare and to reconcile. Therefore, CDC has developed a draft set of items to be proposed as standard survey questions on the topics of sexual behavior, HIV testing, drug use, and other behaviors related to risk of contracting HIV and/or STDs. As part of this effort, CDC will sponsor a telephone-based pretest of 150 households, selected randomly from within an urban area, in order to test these questions.

Further, because some of the survey questions are private and potentially sensitive, the project will entail the testing of a survey administration mode: Telephone-based audio computer-assisted self-interview (T–ACASI), in which a computer will be used to administer the most sensitive questions, and in which the surveyed individual enters responses directly onto the telephone keypad. This procedure eliminates the need for communication of sensitive questions from the interviewer to the respondent, as well as the need for respondents to answer the questions verbally. In order to test the effectiveness of this procedures, half of the interviews will be conducted using the T–ACASI procedure for the most sensitive questions, and half using standard, interviewer-based administration of all questions. Data analysis will rely on an assessment of the response rate under each mode, and on the nature of the data obtained to the sensitive questions.

Information and data obtained from this evaluation will help direct future surveys by determining whether it is feasible to attempt to administer these standard risk questions using a telephone survey and whether a T–ACASI-based procedure represents a technological innovation that will positively contribute to such an effort, through improvements in data quality.

The total cost to respondents is $505.60. The Annual Burden hours are 63.2.

Respondents	Number of respondents	Number of responses/respondent	Avg. burden per response (in hours)
Screening	660	1	0.02
Interview	150	1	0.33

Dated: April 26, 2000.

Charles W. Gollmar,

Acting Associate Director for Policy, Planning and Evaluation Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 DAY–24–00]

Agency Forms Undergoing Paperwork Reduction Act Review

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Proposed Projects

1. Surveillance and Evaluation of Plasma Donors for the Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV)—New—National Center for HIV, STD, and TB Prevention (NCHSTP). In 1987, the President directed the Department of Health and Human Services (DHHS) to determine the nationwide incidence of, to predict the future of, and to determine the extent to which human immunodeficiency virus (HIV) was present in various segments of the population. In response, the CDC formed an epidemiologic team to summarize existing information. An extensive review of published and unpublished data led to the conclusion that even though there was information suggesting a very large number of Americans were infected, there was no substitute for carefully and scientifically obtained incidence and prevalence data. The need to monitor HIV seroprevalence existed on the national and at the state and local levels for public health management: targeting and evaluating prevention programs, planning future health care needs and determining health policy. Research has also indicated that similar studies are needed to determine the incidence and prevalence of hepatitis C (HCV) infection.

A complementary family of surveys and studies, organized by the CDC, provides empirical estimates of the extent of the epidemic of the human immunodeficiency virus (HIV) in the United States. The national surveillance system of HIV infection in the United States includes monitoring incidence and prevalence rates of HIV-infection among first time and repeat whole blood donors. Although this surveillance system has been in place for several years to monitor HIV trends in the United States blood supply, such a

system does not exist for the source plasma industry for either HIV or hepatitis C (HCV).

The source plasma industry collects approximately 14 million of plasma each year. The majority of source plasma is used to produce immune globulins, albumin and other blood products utilized in the United States and in other countries. Donors may donate up to two times per week and are remunerated for each donation. Although the source collection industry plays an important role in the production of blood products, little information regarding HIV or HCV rates within the industry has been published to date.

The objectives of this study of HIV and HCV in plasma donors are to:

1. Analyze the risk behavior characteristics of infected donors to assess distribution and trends of HIV and HCV;

2. Study the motivations and risk factors of HIV and HCV infected deferred donors in order to improve the donor screening and deferral processes;

3. Monitor additional human immunodeficiency and hepatitis viruses, HIV and HCV genetic variation, and other infections relevant to the epidemiology of HIV and HCV among U.S. plasma donors;

4. Evaluate the laboratory characteristics of plasma from infected donors to determine the effectiveness of current and anticipated test modalities; and

5. Evaluate risk factors for transmission of HCV among recently infected individuals.

The above objectives will be attained though a questionnaire designed to evaluate demographic information, knowledge of HIV and HCV, risks for HIV and HCV and motivations for donating plasma. In order to elucidate risks for transmission among this population, a group of HIV and HCV negative persons will also be given the questionnaire. Respondents will be interviewed with the aid of a computer assisted telephone interview (CATI) and respondents will receive a stipend for their time and travel expenses. Participation is voluntary, and all information will be gathered only after written informed consent has been obtained.

The CDC anticipates 430 individuals will be enrolled annually in this study (based upon combined estimates obtained from the plasma companies regarding the number of HIV and HCV positive donors identified per year, plus the number of HIV and HCV negative individuals enrolled as comparisons). It has been estimated that the interview will take approximately 20 minutes to complete; therefore, the response burden will be 143 hours. The approximate hourly wage earned per respondent is $10.00/hour. The total cost to the respondents would be $1430.00. The Annual Burden hours are 218.

Respondents	No. of respondents	No. of responses/ respondent	Avg. burden per response (in hrs.)
Questionnaire	430	1	20/60
Form	90	5	10/60

Dated: April 26, 2000.

Charles W. Gollmar,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 DAY–27–00]

Agency Forms Undergoing Paperwork Reduction Act Review

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Proposed Projects

1. Importation of Etiologic Agents and Packaging and Handling Infectious Substances and Select Agents—(0920–0199)—Extension—Interstate shipment of etiologic agents are regulated by 42 CFR Part 7. This rule establishes minimal packaging requirements for all viable microorganisms, illustrates the appropriate shipping label, and provides reporting instructions regarding damages packages and failure to receive a shipment. In recent years the threat of illegitimate use of infectious agents has attracted increasing interest from the perspective of public health. The Centers for Disease Control and Prevention (CDC) is concerned about the possibility that the interstate transportation of certain infectious agents could have adverse consequences for human health and safety. CDC has already requested that all those entities that ship dangerous human infectious agents exercise increased vigilance prior to shipment to minimize the risk of illicit access to infectious agents. Of special concern are pathogens and toxins causing anthrax, botulism, brucellosis, plague, Q fever, tularemia, and all agents classified for work at Biosafety Level 4. This information collection ensures that selected infectious agents are not shipped to parties ill-equipped to handle them appropriately, or who do not have legitimate reasons to use them and to implement a system whereby scientists and researchers involved in legitimate research may continue transferring and receiving these agents without undue burdens. Respondents include laboratory facilities such as those operated by government agencies, universities, research institutions, and commercial entities. This request is for the information collection requirements contained in 42 CFR 71.54, 72.3(e) and 72.4 relating to the importation and shipment of etiologic agents. Total annual hours burden are 1,925.

CFR Section	No. of respondents	No. of responses/ respondent	Avg. burden/ response (in hrs.)
Application for Permit	2,000	1	20/60