

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).*  
[FR Doc. 00-10978 Filed 5-2-00; 8:45 am]  
BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[30 DAY-27-00]**

**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. 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

CFR Section	No. of respondents	No. of responses/ respondent	Avg. burden/ response (in hrs.)
72.3(e) .....	50	1	6/60
72.3(f) .....	200	10	12/60
72.4 .....	20	1	12/60
72.6(a) .....	100	1	210/60
72.6(d) .....	300	2	30/60
72.6(e) .....	300	2	10/60
72.6(f) .....	300	2	10/60

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[FR Doc. 00-10979 Filed 5-2-00; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30 DAY-28-00]

### Agency Forms Undergoing Paperwork Reduction Act Review

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### Proposed Projects

1. Chronic Fatigue Syndrome (CFS) Surveillance and Related Studies, Prevalence and Incidence of Fatiguing Illnesses in Sedgwick County, Kansas (0920-0401)—Extension—The Centers for Disease Control and Prevention (CDC) A Population-Based CFS Study was done previously in Kansas in 1997. Data from this cross-sectional, random-

digit-dial survey of prolonged fatiguing illness in Wichita, Kansas will be added to the data previously obtained during the past 24 months from this population.

The proposed study continues the Sedgwick County study using identical methodology and data collection instruments. Beginning with a random-digit-dial telephone survey to identify previously identified fatigued and non-fatigued individuals, followed by a detailed telephone interview to obtain additional data on participants' health status during the last 12-month period. Study objectives remain to refine estimates of CFS in Wichita, identify similarities and differences among fatigued and non-fatigued subjects and to describe the clinical course of fatiguing illness in the population. Total annual hours burden are 2,066.

Form name	No. of respondents	No. of responses/ respondent	Avg. burden/ response (in hrs.)
Telephone Questionnaire .....	4,500	1	20/60
Self-Administered Questionnaire—Initially Fatigued Adult .....	75	1	20/60
Self-Administered Questionnaire—Follow-up Fatigued Adult .....	147	1	20/60
Self-Administered Questionnaire—Non Fatigued Adult .....	93	1	30/60
Self-Administered Questionnaire—Initially Fatigued Adolescent .....	2	1	30/60
Self-Administered Questionnaire—Parent of Initially Fatigued Adolescent .....	2	1	30/60
Self-Administered Questionnaire—Follow-up Fatigued Adolescent .....	2	1	30/60
Self-Administered Questionnaire—Parent of Follow-up Fatigued Adolescent .....	2	1	30/60
Self-Administered Questionnaire—Non-Fatigued Adolescent .....	1	1	30/60
Self-Administered Questionnaire—Parent of Non-Fatigued Adolescent .....	1	1	30/60
Symptom Questionnaire—Initially Fatigued Adult .....	75	1	10/60
Symptom Questionnaire—Follow-up Fatigued Adult .....	147	1	10/60
Symptom Questionnaire—Initially Fatigued Adolescent and Parent of Fatigued Adolescent ....	4	1	10/60
Symptom Questionnaire—Follow-up Fatigued Adolescent and Parent of Fatigued Adolescent	4	1	10/60
Course of Fatiguing Illness Questionnaire .....	208	1	4/60
Diagnostic Interview Schedule—Adults Questionnaire .....	315	1	45/60
Diagnostic Interview Schedule—Parent Version .....	5	1	45/60
Diagnostic Interview Schedule—Child Version .....	5	1	45/60
Sleep Disorders Questionnaire—Fatigued Adults .....	222	1	7/60
Fatigue Questionnaire—Adults and Adolescents .....	226	1	15/60
Fatigue Questionnaire—Parent of Adolescent .....	4	1	15/60
SF-36 Questionnaire .....	320	1	11/60