DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–03–95]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498–1210.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: Increasing Cervical Cancer Screening in Never/Rarely Screened, Black Women: Phase I—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Black women in the United States have higher incidence of cervical cancer than White women and higher mortality from cervical cancer than White women. Cancer mortality data from 1974–1994 for Black women show stable, geographic patterns of cervical cancer mortality predominantly in the southeastern part of the United States. While screening rates of Black women are shown to be similar to White women, subgroups of Black women may remain unscreened or under-screened (more than three years since last Pap test), specifically those who are medically uninsured or underinsured or live in rural areas of the country. Screening rates are particularly low for women without access to health care.

The purpose of this project is to conduct formative research to better understand why some Black women ages 40 to 64 do not participate in cervical cancer screening. The proposed study will use focus groups and personal interviews to gather information that will be used to guide future intervention strategies to increase cervical cancer screening in never or rarely screened Black women. There will be no cost to respondents.

Respondents	No. of respondents	No. of responses per respondent	Average burden per responses (in hrs.)	Total burden (in hrs.)
Black women ages 40–64	240	1	90/60	360
Total				360

Dated: July 10, 2003.

Thomas A. Bartenfeld,

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

[FR Doc. 03–17943 Filed 7–15–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–03–96]

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Proposed Project: Final Evaluation of the Effectiveness of Targeted Lookback for Identifying Transfusion Recipients Who Receive Blood That May Have Been Contaminated with Hepatitis C Virus—New—National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC).

In 1998 the Food and Drug Administration (FDA) issued guidelines to blood collection establishments and transfusion services for the notification of persons who received blood or blood components from donors who subsequently tested positive for antibody to hepatitis C virus (anti-HCV) using a licensed multiantigen screening assay. Blood collection establishments were to identify potentially HCV-contaminated blood products and inform transfusion services of these units. The transfusion services were then to attempt to notify the recipients of these products and encourage these recipients to be tested for HCV infection. Recently, the FDA revised their original guidance, extending the lookback period for these multiantigen screened donors and including in the lookback process donors who tested anti-HCV positive using an earlier single-antigen screening assay [1].

[1] Food and Drug Administration. Guidance For Industry. ''Lookback'' for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification,

Continued

CDC, in collaboration with the FDA, has been charged with the responsibility of evaluating this nationwide notification process. An interim nationwide survey (0920–0462) of blood collection establishments and transfusion services was conducted in December 1999 to determine the progress that had been made to date and summarize the lookback results. The objective of this study is to resurvey the blood collection establishments and transfusion services to obtain final results and assess the overall effectiveness of the targeted lookback for identifying persons infected with HCV. The evaluation has two specific aims:

1. Determine the effectiveness of targeted lookback for identifying prior transfusion recipients with HCV infection, including the proportion of recipients identified who are still alive, the proportion of those alive who were successfully notified, the proportion of those notified who have already been tested, the proportion of those notified who get tested as a result of the notification, and the proportion of those tested who are HCV positive.

2. Determine the cost-effectiveness of targeted lookback, including resources (person-hours, costs of recipient notification and testing, etc.) utilized by blood collection establishments and transfusion services for implementation of the lookback protocol.

The evaluation will comprise the following components:

1. A nationwide survey of blood collection establishments.

2. A nationwide survey of transfusion services.

The total cost to respondents is their time to complete the survey.

Respondents	No. of respondents	No. of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Blood collection establishment	140	1	5	700
Transfusion services	5,000	1	5	25,000
Total				25,700

Dated: July 10, 2003

Thomas A. Bartenfeld,

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

[FR Doc. 03–17944 Filed 7–15–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Detection of Mutational Frequency in Human Bone Marrow

Neal S. Young *et al.* (NHLBI)

DHHS Reference No. E–320–2002 filed 06 Nov 2002

Licensing Contact: Fatima Sayyid; 301/435–4521; *sayyidf@mail.nih.gov*

To date there have been no adequate methods to determine the frequency of mutations in humans. This invention discloses a method of measuring the mutational frequency of a mitochondrial DNA sequence by sequencing mitochondrial DNA from clonally expanded single cells such as CD34+ human stem cells. Sequencing for mitochondrial DNA polymorphisms and mutations may also be useful as a general method to detect minimal residual disease in leukemia. The mitochondrial genome is particularly susceptible to mutations and these may be used to measure genomic mutagenesis by virtue of comparison. The application of this invention includes the determination of mutational frequency after chemotherapy, radiation, environmental toxic exposure and genetic disease. The invention also provides a screening for an agent that has a mutagenic effect on a cell.

Structurally Rigid Dopamine D3 Receptor Selective Ligands as Cocaine and Methamphetamine Abuse Therapeutics

Amy Newman *et al.* (NIDA)

DHHS Reference No. E–251–2002/0–US–01 filed 14 Sep 2002

Licensing Contact: Norbert Pontzer; 301/435–5502; *np59n@nih.gov*

The dopamine D3 receptor subtype has been implicated in a number of central nervous system (CNS) disorders including but not limited to drug abuse, schizophrenia and Parkinson's disease. Since D3 receptor ligands show efficacy in animal models of cocaine self-administration and Parkinson's disease, there has been a significant effort to design and develop novel dopamine D3 ligands. However most currently known compounds are highly lipophilic, leading to poor bioavailablility and toxicity, or are not highly D3 selective.

The present invention provides a family of structurally rigid, potent and selective D3 receptor antagonists and partial agonists with lowered lipophilicity. Bioavailable compounds that bind with high affinity and selectivity to D3 receptors can not only provide important tools with which to study the structure and function of this receptor subtype, but may also have therapeutic uses in psychiatric, behavioral and neurologic disorders. More information on these potential therapeutic agents was recently published in Newman et al., Bioorganic

Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV Rockville, MD: Center for Biologics Evaluation and Research (CBER), December 2001.