Ethnic Factors in the Acceptability of Foreign Clinical Data'' (63 FR 31790, June 10, 1998). The E5 guidance provides recommendations to permit the clinical data collected in one region to be used in the registration or approval of a drug or biological product in another region, while allowing for the influence of ethnic factors. The E5 guidance defines ethnic factors that could affect drug response in terms of both intrinsic and extrinsic issues. Because there is the potential for differences in the safety and efficacy of pharmaceutical products among population subgroups, the E5 guidance provides a general framework for how to evaluate medicines with regard to ethnic factors.

II. Scope of Discussion

In view of the background information presented in section I of this document, FDA is requesting comment on the advantages and disadvantages of collecting race and ethnicity data in postmarketing adverse event reports. FDA is also seeking feedback on whether the MedWatch forms should be amended to collect this data based on the standardized categories described in section I.B of this document. Specific comments are being sought on the following questions:

1. Should the MedWatch forms (Forms FDA 3500A and 3500) be amended with a special field or fields to capture adverse event data on race and ethnicity?

2. Should MedWatch race and ethnicity data distinguish between self-reported and observer-reported designations? If so, how should the designations be captured?

3. Would collection of race and ethnicity data on the MedWatch forms have an impact on the ICH E2B guidance relating to the electronic submission of adverse event reports (''E2B Data Elements for Transmission of Individual Case Safety Reports'' (63 FR 2396 at 2397, January 15, 1998))?

4. What is the financial impact associated with adding a special field or fields to the MedWatch forms to collect data on race and ethnicity?

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–30300 Filed 12–5–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for the opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed grant information collection activity or to obtain a copy of the data collection plan and draft instruments, call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of grantee functions including whether the information will 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.

Proposed Project: Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Title I Minority AIDS Initiative (MAI) Annual Plan and Title I MAI Annual Report: New

The CARE Act (codified under Title XXVI of the Public Health Service Act) was first enacted by Congress in 1990, and reauthorized in 1996 and 2000. It addresses the unmet health needs of persons living with HIV by funding primary health care and support services that enhance access to and retention in care. The CARE Act funded services reach over 500,000 individuals; after Medicaid and Medicare, it is the largest single source of Federal funding for HIV/AIDS care for low-income, uninsured, and underinsured Americans. Title I under the CARE Act provides emergency assistance to eligible metropolitan areas (EMAs) the most severely affected by the HIV epidemic, for the purpose of providing a continuum of high quality, community-based care for low-income individuals and families with HIV disease.

In response to a Presidential declaration in 1998 that HIV was a severe and ongoing health crisis among minority communities, the Congress directed a portion of fiscal year (FY) 1999 CARE Act funds to a new Minority AIDS Initiative (MAI) to address the disproportionate impact of HIV on African-American and Hispanic communities. Since then, the focus has been broadened to include all racial and ethnic minority communities. HRSA disburses the Title I component of MAI funds among the 51 EMAs based on a congressionally mandated formula.

The Congress has directed that Title I MAI funds be used through established local planning council processes to improve HIV-related health outcomes for communities of color and reduce existing health disparities. Improved health outcomes include reducing HIV transmission, morbidity and opportunistic disease, and improving life expectancy.

The Title I MAI Annual Plan (Plan) and Title I MAI Annual Report (Report) are designed to collect information from grantees on MAI-funded services, the number and demographics of clients served, and client-level outcomes. This information is needed to monitor and assess: (a) Increases and changes in the type and amount of HIV/AIDS health care and related services being provided to each disproportionately impacted community of color; (b) increases in the number of persons receiving HIV/AIDS services within each racial and ethnic community; and (c) the impact of the Title I MAI funded services in terms of client-level and service-level health outcomes. This information also will be used to plan new technical assistance and capacity development activities, and inform the HIV/AIDS Bureau/HRSA policies and program management.

The Plan and Report will be transmitted by mail and electronically to all Title I grantees and made available through the HRSA web site. Two alternatives will be provided to grantees for submitting Plans and Reports electronically: a designated mailbox for e-mailed electronic reports and a web-based reporting option. The Plan and

Report forms will be linked to reduce the reporting burden, and are designed to include check box responses, fields for reporting budget, expenditure and client data, and open-ended text boxes for describing client or service-level outcomes. The forms will automatically generate totals and percentages and include other automated fields to minimize the time required to complete the Plan and Report, and include built-in checks to minimize possible reporting errors.

The forms will require grantees to collect client, services, and outcomes information from MAI-funded service providers (sub-grantees), which grantees have already been collecting from MAI-funded providers since FY 2000. It will take grantees no longer than 15 minutes to complete a single form (response) for each MAI-funded service provided to each minority racial or ethnic minority community.

In FY 2002, grantees would have completed an average of nine forms/responses to prepare their Title I Annual MAI Plans and eight forms/responses to prepare their Title I Annual MAI Reports. For FY 2003, the average number declined to eight and seven forms/responses respectively. Thirty-eight of the 51 grantees (75%) would have completed 10 or fewer Plans and 10 or fewer Reports during both fiscal years.

Therefore the approximate response burden for Title I grantees in completing *both* the Annual MAI Plan and the Annual MAI Report is estimated as:

Estimated number of grantee respondents	Estiamted responses per grantee	Total number of responses	Hours per response	Estimated total hour burden
51	15	765	.25	191.25

Send comments to Susan G. Queen, PhD, HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 day of this notice.

Dated: November 28, 2003.

Jon L. Nelson,

Associate Administrator for Management and Program Support.

[FR Doc. 03–30303 Filed 12–5–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclose of which constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Computational Models of Saccades.

Date: December 4, 2003.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Michael A. Steinmetz, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5172, MSC 7844, Bethesda, MD 20892, (301) 435–1247, *steinmem@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel Sleep.

Date: December 4, 2003.

Time: 12 p.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Daniel R. Kenshalo, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5176, MSC 7844, Bethesda, MD 20892, (301) 435–1255, *kenshalod@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 PTHA 04 S: Vascular Calcification.

Date: December 5, 2003.

Time: 1:30 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Larry Pinkus, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435–1214.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Functional Proteomic Analysis of Cardiac Mitochondria.

Date: December 5, 2003.

Time: 1:30 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Anshumali Chaudhari, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892, (301) 435–1210.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel Neuroendocrine Control.

Date: December 9, 2003.

Time: 12 p.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Daniel R. Kenshalo, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5176, MSC 7844, Bethesda, MD 20892, (301) 435–1255, *kenshalod@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel ZRG1 CNNT 05M: Member Conflict: Brain Disorders and Clinical Neurociences IRG.

Date: December 10, 2003.

Time: 12 p.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: William C. Benzing, PhD, Scientific Review Administrator, Center for