

clinical trial design and analysis plan meet defined objectives.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance has been approved under OMB control number 0910–0001 (expires May 31, 2008).

III. Comments

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 The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: September 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–18512 Filed 9–16–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0018] (formerly 02D–0018)

Guidance for Industry on the Collection of Race and Ethnicity Data in Clinical Trials; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Collection of Race and Ethnicity Data in Clinical Trials.” This guidance provides recommendations on a standardized approach for collecting and reporting race and ethnicity information in clinical trials conducted in the United States and abroad for certain FDA regulated products. This document provides guidance on meeting the requirements in the 1998 final rule on Investigational New Drug Applications and New Drug Applications (Demographic Rule) (63 FR 6854, February 11, 1998).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFMA–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Katherine Hollinger, Office of Women's Health, Office of Science and Health Communication (HF–8), 5600 Fishers Lane, Rockville, MD 20857, 301–827–0935, or

Stephen Ripley, Center for Biologics Evaluation and Research (HFMA–17), 1401 Rockville Pike, Rockville, MD 20852, 301–827–6210, or Investigational Device Exemption Staff (HFV–403), Center for Devices and Radiological Health, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Collection of Race and Ethnicity Data in Clinical Trials.” A draft of this guidance was issued on January 30, 2003 (68 FR 4788). Based on comments received on the draft and the refinement of agency thinking on this topic, FDA has revised the draft guidance and is now issuing a guidance. This guidance is intended to assist sponsors in the collection of race and ethnicity information in clinical trials conducted in the United States and abroad for certain FDA regulated products using a standardized approach. The standardized approach was developed by the Office of Management and Budget (OMB). FDA believes that the use of the OMB approach will facilitate comparisons across clinical studies analyzed by FDA and data collected by other Federal agencies. Although FDA has long requested the racial and ethnic ancestral origins of subjects in certain clinical trials, the agency is now making recommendations on the methods and categories to use when collecting and reporting data. The Department of Health and Human Services (HHS) issued a 1999 report entitled “Improving the Collection and Use of Racial and Ethnic Data in HHS,” in which HHS announced the adoption of OMB Directive 15 as part of its policy on collecting and reporting data on racial and ethnic ancestral origins.

FDA received several comments in response to the January 2003 draft guidance and has made some clarifying changes in the final version of the guidance. Specifically, we have:

1. Added reference to 21 CFR 314.50(d)(5)(v) to include studies for efficacy.
2. Clarified the traceability/mapping between more granular characterizations for racial and ethnic ancestral origins: “When more detailed characterizations are desired, the use of Race and Ethnicity vocabulary tables located within Health Level Seven's Reference Information Model Structural Vocabulary Tables is recommended. These tables provide the five and two OMB characterizations traceable to more detailed characterizations and concept

ID code sets and this will ensure that traceability is consistent.”

3. Added text to address gaps in the characterization of race and ethnicity: “Where gaps exist in the representation of race or ethnicity categories, sponsors are encouraged to discuss the race or ethnicity issue with the appropriate review division.”

4. Added text to allow omission of characterization of Hispanic or Latino ethnicity for international clinical trials: “the ethnicity question can be omitted for studies conducted abroad.”

5. Changed the characterization of “Black, of African heritage,” to “Black” for studies conducted abroad.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the agency’s current thinking on collection of race and ethnicity data in clinical trials. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

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III. Electronic Access

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Dated: September 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–18595 Filed 9–16–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 552b(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 disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel Interferon-Alpha in Type 1 Diabetes.

Date: October 4, 2005.

Time: 1 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, 3256, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Mercy R. PrabhuDas, PhD., Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–451–2615, mp457n@nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel Center For AIDS Research: D–CFAR, CFAR.

Date: October 6–7, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Barney Duane Price, PhD, Scientific Review Administrator, Scientific Review Program, DHHS/NIH/NIAID/DEA, Room 3265, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–451–2592, pricebd@niaid.nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel STD Prevention Study.

Date: October 11, 2005.

Time: 12 p.m. to 2 p.m.

Agenda: To provide concept review of proposed grant applications.

Place: National Institutes of Health, Building 16, 16 Center Drive, Bethesda, MD 20892.

Contact Person: John A. Bogdan, PhD, Scientific Review Administrator, Scientific

Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–496–2550, jbogdan@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 12, 2005.

Anthony M. Coelho, Jr.,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–18600 Filed 9–16–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(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 disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Allergy, Immunology, and Transplantation Research Committee Allergy, Immunology and Transplantation Research Committee

Date: October 17, 2005.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Quirijn Vos, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC, 7616, Bethesda, MD 20892–7616, (301) 451–2666, qvos@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)