

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3130, MSC 7850, Bethesda, MD 20892, (301) 435-3009, elliottro@csr.nih.gov.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group, Pregnancy and Neonatology Study Section.

Date: February 17-18, 2005.

Time: 8 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Michael Knecht, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6176, MSC 7892, Bethesda, MD 20892, (301) 435-1046, knechtm@csr.nih.gov.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group, Neurotoxicology and Alcohol Study Section.

Date: February 17-18, 2005.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Joseph G. Rudolph, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7844, Bethesda, MD 20892, (301) 435-2212, josephru@csr.nih.gov.

Name of Committee: Hematology Integrated Review Group, Hemostasis and Thrombosis Study Section.

Date: February 17-18, 2005.

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

Agenda: To review and evaluate grant applications.

Place: Four Points by Sheraton Bethesda, 8400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jerrold Fried, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2114, MSC 7840, Bethesda, MD 20892, (301) 435-2633, friedje@csr.nih.gov.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group Macromolecular Structure and Function C Study Section.

Date: February 17-18, 2005.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue, NW., Washington, DC 20036.

Contact Person: Arnold Revzin, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4184, MSC 7824, Bethesda, MD 20892, (301) 435-1153, revzina@csr.nih.gov.

Name of Committee: Health of the Population Integrated Review Group Epidemiology of Chronic Diseases Study Section.

Date: February 17-18, 2005.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: J. Scott Osborne, PhD, MPH, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4114, MSC 7816, Bethesda, MD 20892, (301) 435-1782, osbornes@csr.nih.gov.

Name of Committee: Cardiovascular Sciences Integrated Review Group Cardiovascular Differentiation and Development Study Section.

Date: February 17-18, 2005.

Time: 8:30 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham Washington, DC, 1400 M Street, NW., Washington DC 20005.

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, pinkusl@csr.nih.gov.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group Genetic Variation and Evolution Study Section.

Date: February 17-18, 2005.

Time: 9 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: The River Inn, 924 25th Street, NW., Washington DC 20037.

Contact Person: David J. Remondini, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2210, MSC 7890, Bethesda, MD 20892, 301/435-1038, remondid@csr.nih.gov.

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

Date: February 17, 2005.

Time: 3 p.m. to 4 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: Fouad A. El-Zaatari, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, MSC 7808, Bethesda, MD 20892, (301) 435-1149, elzaataf@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 13, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-1273 Filed 1-24-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Public Comment Period

SUMMARY: The National Institute of Biomedical Imaging and Bioengineering (NIBIB) is developing its first 5-year strategic plan (2005-2009), and invites the public to provide input regarding NIBIB's areas of scientific emphasis, operational emphasis, and strategic priorities. The public is invited to provide comments via the NIBIB Web site.

Background

The NIBIB was authorized by Public Law 106-580, which was signed into law by President William Clinton on December 29, 2000. The establishment of NIBIB provided an identity and a research home for the development and application of new technologies and techniques for the delivery of health care in the 21st century.

The mission of the NIBIB is to improve human health by leading the development and accelerating the application of biomedical technologies. The Institute is committed to integrating the engineering and physical sciences with the life sciences to advance basic research and medical care.

To accomplish this mission, the NIBIB has developed a set of goals, strategies, and objectives designed to maximize the Institute's impact on human health. These goals, strategies, and objectives provide the framework and action plan for the Institute's direction over the next five years, and determine how NIBIB will allocate resources to support and enhance scientific research.

Request for Comments

The NIBIB wants to develop a process that considers the views of groups and individuals who are concerned about the Institute's programs. The public is invited to provide input electronically into the development of NIBIB's strategic plan for 2005-2009. Please visit the NIBIB Web site at <http://www.nibib1.nih.gov/about/SP/strategicplan.htm> to comment.

Comments Due Date

We are asking that electronic comments regarding the development of NIBIB's strategic plan be received by February 28, 2005. If you do not have access to a computer, the NIBIB will provide you with a copy of the material that is on the Web site. You may request

this material from Ms. Colleen Guay-Broder, Office of Science Policy and Public Liaison, NIBIB, NIH, 31 Center Drive MSC 2281, Room 1C14, Bethesda, MD 20892-2281.

The NIBIB looks forward to working with the research community and the public to develop its strategic plan.

Dated: January 14, 2005.

Colleen Guay-Broder,

Director, Office of Science Policy and Public Liaison, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health.

[FR Doc. 05-1278 Filed 1-24-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Mandatory Guidelines: Response to Public Comments.

SUMMARY: In the *Federal Register* notice of April 13, 2004 (69 FR 19644), the Department of Health and Human Services ("HHS" or "Department") published final changes to the Mandatory Guidelines for Federal Workplace Drug Testing Programs. These changes established specimen validity testing standards and reporting procedures for Federal agency urine specimens collected under the Mandatory Guidelines for Federal Workplace Drug Testing Programs. These changes to the Mandatory Guidelines were subject to further comment only on the creatinine criterion that is part of the requirement to report a urine specimen as substituted because the Department based this criterion on information received after the comment period on the proposed changes published on August 21, 2001 closed. After reviewing the comments received regarding this issue, the Department has concluded that the 2 mg/dL creatinine criterion established in the April 13, 2004, *Federal Register* notice (69 FR 19644) for a substituted specimen is the appropriate cutoff concentration to use for reporting a urine specimen as substituted.

EFFECTIVE DATE: November 1, 2004.

FOR FURTHER INFORMATION CONTACT: Walter F. Vogl, Ph.D., Division of Workplace Programs, SAMHSA, Room #2-1035, 1 Choke Cherry Road,

Rockville, Maryland 20857, telephone (240) 276-2600, fax (240) 276-2610, or e-mail: walter.vogl@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) establish the scientific and technical guidelines for Federal workplace drug testing programs and standards for certification of laboratories engaged in urine drug testing for Federal agencies, under authority of section 503 of Pub. L. 100-71, 5 U.S.C. 7301 note, and E. O. No. 12564. The Mandatory Guidelines were first published in the *Federal Register* on April 11, 1988 (53 FR 11979), revised on June 9, 1994 (59 FR 29908), revised on November 13, 1998 (63 FR 63483), and revised on April 13, 2004 (69 FR 19644).

The April 13, 2004, *Federal Register* notice finalized the changes to the Mandatory Guidelines that were proposed in the *Federal Register* notice published on August 21, 2001 (66 FR 43876); established an effective date of November 1, 2004; but allowed further public comment on one issue. That is, comments were requested on the 2 mg/dL creatinine concentration criterion that was established as part of the requirement to report a urine specimen as substituted. This was left open for comment because the 2 mg/dL concentration level was based on information received after the comment period closed on the *Federal Register* notice published on August 21, 2001. The additional information that was provided indicated that it was possible for an individual to provide a normal urine specimen with a creatinine concentration less than the 5 mg/dL cutoff concentration criterion proposed in the August 21 notice.

II. Discussion of Public Comments

As stated in the April 13, 2004, *Federal Register* notice, the Department was only accepting comments on the creatinine criterion. The Department did receive several comments on other sections of the Mandatory Guidelines including the effective date, but these sections and the effective date were not open to comment.

Several commenters recommended that the Department take one or more of the following actions with regard to the creatinine criterion:

Comment: Immediately collect another specimen from the donor when the creatinine concentration is between 2 mg/dL and 5 mg/dL because this policy will continue to detect "truly substituted" specimens.

Response: The suggestion that a urine specimen with a creatinine concentration between 2 mg/dL and 5 mg/dL is "truly substituted" implies that the cutoff concentration should be raised to 5 mg/dL to ensure that all substituted specimens are correctly identified as substituted specimens. The Department disagrees with this suggestion. At the Department of Transportation Federal Aviation Administration's conference held February 4-6, 2003, to study substitution and adulteration issues, the experts attending the conference were convinced based on evidence presented that it was possible for some individuals to produce a valid urine specimen with a creatinine concentration of less than 5 mg/dL, the level specified in the *Federal Register* notice of August 21, 2001. After consideration of data on creatinine levels, they concluded that the level should be set at 2 mg/dL. Lowering the concentration level will prevent the likelihood of individuals being falsely accused of substituting their specimen. The Department also notes that there is a second criterion for determining whether a specimen has been substituted—specific gravity—which has not been changed.

Comment: Immediately collect another specimen from the donor when the creatinine concentration is between 2 mg/dL and 5 mg/dL because approximately one half of the second specimens collected from donors in this creatinine range are tested and reported drug positive.

Response: The commenter who submitted this comment did not provide actual data to justify the claim that approximately one-half of the second specimens collected are tested and reported drug positive. The commenter based the observation on specimens between 2 mg/dL and 5 mg/dL that one Medical Review Officer ordered to have a second specimen collected. There was no indication of the number of specimens that were recollected, the reason for testing (*i.e.*, random, post-accident, pre-employment), or whether they were Federal agency, DOT regulated, or private-sector specimens. The commenter did say that all of the recollections that were drug positive were from males and none from females. The Department believes this anecdotal information is not sufficient justification to require immediately collecting a second specimen from a Federal employee or applicant for a Federal agency testing designated position using a direct observed collection. The Department also believes that a urine specimen that tests negative for drugs, is dilute, and exhibits no other evidence of