

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Proposed Revision of Approved Collection; Comment Request; Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought, 42 CFR Part 50, Subpart F and for Responsible Prospective Contractors, 45 CFR Part 94

Summary: 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 Office of the Director (OD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of

Management and Budget (OMB) for review and approval.

Proposed Collection:

Title: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and for Responsible Prospective Contractors, 42 CFR Part 50, Subpart F, and 45 CFR Part 94.

Type of Information Collection

Request: Revision of OMB No. 0925-0417, expiration date November 30, 2008.

Need and Use of the Information

Collection: This is a request for OMB Approval for the information collection and recordkeeping requirements contained in the final rule 42 CFR Part 50, Subpart F and related recordkeeping requirements regarding contractors in Responsible Prospective Contractors, 45 CFR Part 94. The purpose of these regulations is to promote objectivity in research by requiring institutions to establish standards to ensure that there

is no reasonable expectation that the design, conduct, or reporting of research will be biased by a conflicting financial interest of an investigator.

Frequency of Response: On occasion.

Affected Public: Individuals or households; business or other for-profit; not-for-profit institutions; State, Local or tribal government.

Type of Respondents: Any public or private entity or organization. The annual reporting burden is as follows:

Estimated Number of Respondents: 67,860;

Estimated Number of Responses Per Respondent: 1.60;

Averaged Burden Hours per Response: 3.40; and

Estimated Total Annual Burden Hours Requested: 220,280.

The annualized cost to the public is estimated at \$8,120,000.

Operating Costs and/or maintenance costs are \$4,633.00.

TABLE—ESTIMATES OF HOUR BURDEN

Type of respondents based on applicable section of regulation	Number of respondents	Frequency of response	Average burden hours per response	Annual hour burden
Reporting:				
Initial Reports under 42 CFR § 50.604(g)(2) or 45 CFR 94.4(g)(2) from Institutions	ⁱ 300	1	80	24000
Subsequent Reports under 42 CFR § 50.604(g)(2) or 45 CFR 94.4(g)(2) from Institutions	ⁱⁱ 40	1	2	80
Subsequent Reports under 42 CFR § 50.606(a) or 45 CFR 94.6 from Institutions	ⁱⁱⁱ 20	1	10	200
Recordkeeping: Under 42 CFR § 50.604(e) or 45 CFR 94.4(e)—Institutional files	^{iv} 25000	1	4	100000
Disclosure:				
Under 42 CFR § 50.604(a) or 45 CFR 94.4(a)—Institutions	^v 2800	1	20	56000
Under 42 CFR § 50.604(c) or 45 CFR 94.4(c)—Investigators	^{vi} 40000	1	1	40000
Totals	67860	220280

ⁱ Although not more than 300 reports of Financial Conflict of Interest are expected, the responding institutions will need to review all financial disclosures associated with PHS funding awards to determine whether any conflicts of interest exist. Thus, the total burden of 24,000 hours is based upon estimates that it will take on average 4/5 of an hour to review each of 30,000 financial disclosures associated with PHS funding awards. (30,000 × 48 (minutes per file) = 1,440,000 ÷ 60 minutes = 24,000 (total hours).

ⁱⁱ The burden for subsequent reports of conflicts (made during the 12-month period following the initial report) is significantly less, because we do not expect many additional reportable conflicts and there will be only a limited number of disclosures to review.

ⁱⁱⁱ This burden was originally estimated in the 1995 Final Rule to be no more than 5 instances that the failure of an investigator to comply with the institution's FCOI policy has biased the design, conduct or reporting of the research. "Objectivity in Research, Final Rule" 60 Fed. Reg. 132 (July 11, 1995) pps. 35810–35819. This burden estimate, and others, was increased in 2002 "due to increased numbers of institutions and investigators."

^{iv} Assumes 2500 institutions, 10 responses per year per institution.

^v Assumes 2500 institutions, 10 responses per year per institution.

^{vi} Assumes 2800 recipient institutions and 20 hours per institution informing each investigator of institutional policy.

^{vii} The financial disclosure burden estimate is based upon an investigator figure of 40,000 with an average response time of 1 hour. The estimated number of investigators has not changed since the 2002 Information Collection Request associated with the Final Rule. These estimates are for the burden imposed by disclosure, reporting and recordkeeping requirements. Not all activities of institutions related to FCOI result from regulations.

Requests for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) 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; (2) The accuracy of the agency's estimate of the burden (including hours and cost) of the

proposed information collection; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on respondents, including through the

use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

For Further Information Contact: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Ms. Mikia Currie, Assistant Project Clearance Officer, Office of Extramural Research, (OER), Office of Policy for Extramural Research Administration, (OPERA), 6705 Rockledge Drive, Room 1198, Bethesda, MD 20892-7974, or call non-toll-free number 301-435-0941 or e-mail your request, including your address, to: curriem@od.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: May 19, 2008.

Joe Ellis,

Director, Office of Policy for Extramural Research Administration, OER, National Institutes of Health.

[FR Doc. E8-15826 Filed 7-11-08; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney 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: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Diabetes, Erectile Dysfunction and Cardiovascular Diseases.

Date: July 29, 2008.

Time: 3 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy

Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lakshmanan Sankaran, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 755, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7799, ls38oz@nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: July 3, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-15822 Filed 7-11-08; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA-3287-EM]

California; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of California (FEMA-3287-EM), dated June 28, 2008, and related determinations.

DATES: *Effective Date:* July 4, 2008.

FOR FURTHER INFORMATION CONTACT:

Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-2705.

SUPPLEMENTARY INFORMATION: The notice of an emergency declaration for the State of California is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared an emergency by the President in his declaration of June 28, 2008.

Kern, Mariposa, Plumas, and Santa Barbara Counties for emergency protective measures, (Category B), limited to direct Federal assistance, under the Public Assistance program.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant;

97.048, Disaster Housing Assistance to Individuals and Households In Presidential Declared Disaster Areas; 97.049, Presidential Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidential Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E8-15976 Filed 7-11-08; 8:45 am]

BILLING CODE 9110-10-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA-1771-DR]

Illinois Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Illinois (FEMA-1771-DR), dated June 24, 2008, and related determinations.

DATES: *Effective Date:* July 3, 2008.

FOR FURTHER INFORMATION CONTACT:

Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Illinois is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of June 24, 2008.

Whiteside County for Individual Assistance.

Jersey County for Individual Assistance and Public Assistance.

Rock Island County for Individual Assistance (already designated for emergency protective measures [Category B], limited to direct Federal assistance, under the Public Assistance program).

Calhoun County for Individual Assistance and Public Assistance (already designated for emergency protective measures [Category B], limited to direct Federal assistance, under the Public Assistance program).

Adams, Clark, Coles, Crawford, Cumberland, Hancock, Henderson, Jasper, and Lawrence Counties for Public Assistance (already designated for Individual Assistance and emergency protective measures [Category