

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, *OIRA submission @ omb.eop.gov* or by fax to 202-395-6974, Attention: NIH Desk Officer. To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Eileen Newman, Associate Director, National Kidney Disease Education Program, OCPL, NIDDK, NIH, Building 31, Room 9A06, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 435-8116 or Email your request, including your address to: *Eileen.newman@nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are

best assured of having their full effect if received within 30 days of the date of this publication.

Proposed Collection: Evaluation of a Kidney Disease Education Program with Promotores in the Hispanic Community, 0925—NEW, National Kidney Disease Education Program, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH).

Need and Use of Information Collection: NKDEP is developing a kidney disease education program to raise awareness among the Hispanic community at risk for kidney disease. Since diabetes is the most common cause of kidney disease, the program is being developed for inclusion in existing diabetes programs being conducted by “promotores de salud” (Spanish/English-speaking community health workers). A pilot evaluation will assess: (a) Overall quality of the program from the client and promotor/a perspective, including strengths and weaknesses of the program and the

training, and areas for program improvement; (b) effectiveness of the program on the clients (the community members being educated); and (c) effectiveness of materials and training, including promotores’ ability to deliver education to the client and administer the client pre-test/post-test surveys. The pilot study will deliver strategic and actionable guidance for refining the educational and training materials for national dissemination. Based on outcomes from the pilot study, a national evaluation is planned that will use the client pre-test/post-test surveys to assess: (a) Knowledge gains about kidney disease, (b) awareness of NKDEP resources and importance of kidney health, (c) reported behavior change outcomes and (d) reported health status.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 101 (see table below).

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	No. of responses per respondent	Response burden (hours)	Total burden hours
Pilot study collection: Promotores	Promotores training pre-test, post-test, and qualitative in-depth interview post client session (Attachment 1 and 2).	12	1	5/60	1
Promotores	Administer client pre-test, post-test, and second post-tests for experimental and control groups (Attachment 3).	20	17	15/60	85
Client Group	Client pre-test, post-test, second post-test for experimental and control groups (Attachment 3).	85	1	10/60	14
Client Group (partial)	Client qualitative in-depth interview post-client session (Attachment 4).	4	1	10/60	1
Total		121			101

Dated: September 23, 2013.

Camille M. Hoover,

Executive Officer, NIDDK, NIH.

[FR Doc. 2013-23673 Filed 9-26-13; 8:45 am]

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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. App.), 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; HIV Vaccine Research and Design.

Date: October 21–22, 2013.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, Regency Ballroom, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Kelly Y. Poe, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700-B Rockledge Drive, MDS-7616, Bethesda, MD 20892, 301-451-2639, *poe@niaid.nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Peer Review Meeting.

Date: October 21–23, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: Residence Inn Bethesda, Montgomery I & II, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Maja Maric, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, DHHS/NIH/NIAID, 6700B Rockledge Drive,

Room 3266, Bethesda, MD 20892-7616, 301-451-2634, maja.marić@nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Peer Review Meeting.
Date: October 28-29, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: Sheraton—Silver Spring, Cedar Room, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Maryam Feili-Hariri, Ph.D., Scientific Review Officer, Scientific Review Program, DHHS/NIH/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301-594-3243, haririmf@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 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-23526 Filed 9-26-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Dental and Craniofacial Research Special Emphasis Panel; Clinical Trial or Biomarker Clinical Evaluation Study Planning Grant and Clinical Trial Implementation or Biomarker Clinical Evaluation Study Cooperative Agreement Applications Review Panel.

Date: October 21, 2013.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 701, 6707 Democracy Boulevard, Bethesda, MD 20892.

Contact Person: Victor Henriquez, Ph.D., Scientific Review Officer, DEA/SRB/NIDCR, 6701 Democracy Blvd., Room 668, Bethesda, MD 20892-4878, 301-451-2405, henriquv@nidcr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: September 23, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-23527 Filed 9-26-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Commercialization License: The Use of Cysteamine for the Treatment of Pancreatic Cancer, Breast Cancer and Hepatocellular Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, indicates that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive commercialization license to practice the inventions embodied in technology family E-219-2013/0, including U.S. patent application 61/814,010 entitled "A Novel Role of Cysteamine in Suppression of Cancer Invasion and Metastasis and Prolonging Survival of Host Through Inhibition of Matrix Metalloproteinases in Human Cancer" [HHS Ref. E-219-2013/0-US-01], Canadian patent application 2,813,514 entitled "Use of Cysteamine and Derivatives Thereof to Suppress Tumor Metastases" [HHS Ref. E-219-2013/0-CA-02], South Korean patent application 10-2013-43713 entitled "Use of Cysteamine and Derivatives Thereof to Suppress Tumor Metastases" [HHS Ref. E-219-2013/0-KR-03], Australian patent application 2013205350 entitled "Use of Cysteamine and Derivatives Thereof to Suppress Tumor Metastases" [HHS Ref. E-219-2013/0-AU-04], and Mexican patent application MX/a/2013/004423 entitled "Use of Cysteamine and Derivatives Thereof to Suppress Tumor Metastases" [HHS Ref. E-219-2013/0-MX-05]; and all related continuing and foreign patents/patent applications for these technology families, to Raptor Pharmaceuticals, Inc. The patent rights

in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive commercialization license territory may be worldwide, and the field of use may be limited to:

The treatment of pancreatic cancer, breast cancer and hepatocellular carcinoma (HCC) by using compositions containing cysteamine.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before October 28, 2013 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive commercialization license should be directed to: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4632; Facsimile: (301) 402-0220; Email: lambertsond@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

Cysteamine is a naturally occurring degradation product of the amino acid cysteine that is most commonly used for the treatment of cystinosis. The inventors on this technology have demonstrated that cysteamine suppresses the activity of matrix metalloproteinases (MMPs), enzymes that have been implicated in tumor invasion and metastasis. Importantly, administration of cysteamine was able to reduce invasion and metastasis in mouse xenograft tumor models for pancreatic cancer, prolonging the survival of the mice while having no adverse side effects. Based on these findings, cysteamine could represent a novel therapeutic treatment of cancer with fewer side-effects than current therapies.

The prospective exclusive commercialization license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404 within thirty (30) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections