Frequency of Response: One time. *Affected Public:* Individuals or households. *Type of Respondents:* Patients, relatives, friends, and general public. The annual reporting burden is as follows: *Estimated Number of Respondents:* 333,620 for three questions and 166,810 for four questions; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* .0033 for 3 questions and .0083 for 4 questions; and *Estimated Total Annual Burden Hours Requested:* 2,479. The annualized cost to respondents is estimated at: $29,748. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Individuals or households				
—3 questions	333,620	1	.0033	1,094
—4 questions	166,810	1	.0083	1,385
Total				2,479

Request 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 function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (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 those who are to respond, including 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 Chris Thomsen, Chief, Cancer Information Service Branch, Office of Cancer Information, Communication, and Education, National Cancer Institute, NIH, Building 31, Room 10A16, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 496–5583 ext. 239 or E-mail your request, including your address to: *thomsenc@mail.nih.gov*

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before April 7, 2000.

Dated: January 28, 2000.

Reesa Nichols,

OMB Clearance Liaison.

[FR Doc. 00–2629 Filed 2–4–00; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Cooperative Research and Development Agreement (CRADA) To Undertake Research and Development of a Corticotropin Releasing Factor (CRF) Antagonist(s) for the Treatment of Cocaine Dependence

AGENCY: National Institute of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health, is seeking proposals from potential collaborators for a Cooperative Research and Development Agreement (CRADA) to test, by scientific means meeting U.S. Food and Drug Administration (FDA) standards, the hypothesis that Corticotropin Releasing Factor (CRF) antagonists may be useful in the treatment of cocaine dependence. NIDA will consider proposals from all qualified entities and will, subject to negotiation of a mutually agreed upon research plan, provide substantial in kind clinical and preclinical resources with the understanding that the CRADA collaborator will be free to utilize data from the CRADA to pursue regulatory filings in the U.S. and abroad. Subject to negotiation of details in a mutually agreed upon research plan, NIDA will provide the CRADA collaborator with access to its preclinical development components and clinical trials contractual network. No NIH funding may be provided to a collaborator under a CRADA, therefore the collaborator will bear the financial and organizational costs of meeting its obligations under the research plan. It is NIDA's intention to provide, at a minimum, clinical trials services sufficient to permit, subject to FDA approval, research and development up to and including Phase II hypothesis testing trials. Assuming demonstration of safety and efficacy at the conclusion of Phase II trials and subject to negotiation, NIDA will consider undertaking Phase III trials sufficient to permit collaborator to seek a U.S. New Drug Approval (NDA).

DATES: NIDA will consider all proposals received within 90 days of the date of publication of this notice. This notice is active until May 8, 2000.

ADDRESSES: Questions about this notice may be addressed to Mr. Lee Cummings (301–443–1143) or Dr. Frank Vocci (301–443–2711) at the following address: Division of Treatment Research and Development, National Institute on Drug Abuse, 6001 Executive Boulevard, MSC 9551, Bethesda, Maryland 20892–9551.

SUPPLEMENTARY INFORMATION: There is mounting evidence that drugs of abuse effect the brain systems mediating the stress response. Evidence suggests that withdrawal syndromes associated with chronic use of drugs of abuse results in elevations of Corticotropin Releasing Factor (CFR) levels. The effects of chronic opiate and cocaine abuse in human subjects have been studied. Investigators have reported derangements of the stress response, even long after cessation of drug use. Taken together, these results would suggest a role of the CRF system in acute and, possibly, protracted abstinence. A role of stress in relapse to drugs of abuse is strongly suspected.

Stress has been shown to modify the intake of drugs of abuse in preclinical studies of drug self-administration. The effect of stress to increase drug intake has been shown for opiates and cocaine. Moreover, the effects of stress can be mimicked by CRF administration and inhibited by CRF antagonists. The inhibitory effect of CRF antagonists on stress-induced increases in drug-taking behavior is impressively robust. Hence,

further study of the modulation of stress responses by CRF antagonists in drug dependent and formerly dependent subjects and the possible relationship to reduction of drug use or prevention of relapse is a high priority for NIDA.[1] NIDA does not currently own or have access to a CRF antagonist with which to undertake this line of research and development. To this end, NIDA is seeking collaborations with pharmaceutical partners to evaluate CRF antagonists in drug dependent and formerly drug dependent subjects. NIDA is seeking to enter into a Cooperative Research and Development Agreement (CRADA) with a pharmaceutical company or its license, the purpose of which would be to assess the effects of CRF antagonists in drug dependent populations. NIDA is willing to provide both intellectual expertise and preclinical and clinical support in a collaboration. While NIDA would prefer to enter into a CRADA with a company or licensee that is already in clinical testing phase with a CRF antagonist, it would also entertain collaborations involving drug candidates in the preclinical stage of testing. NIDA's Medications Development Program possesses the capacity to perform pharmacological and toxicological testing, pharmacokinetics, dosage form development and clinical testing from Phase I through Phase III testing and is willing to apply these capacities in the assessment of a CRF antagonist.

Selection factors of importance of NIDA include:

(1) It is mandatory that the collaborator have proprietary rights to the CRF antagonist sufficient to permit research and commercial development for the intended field of use, i.e., treatment of cocaine dependence. In the event the collaborator does not own the CRF antagonist, collaborator must provide appropriate documentation of a commercialization license to the field of use sufficient to permit the CRADA to proceed. Collaborator must be able to supply dosage forms of a CRF antagonist made to FDA Good Manufacturing Practices (GMP) standards sufficient to permit each stage of research and development to proceed.

(2) NIDA will consider the amount of research and development documentation and experience already in the collaborator's possession. NIDA will sign appropriate confidential disclosure agreements in order to review proprietary and unpublished data. While NIDA will consider all proposals, it will give a higher priority to proposals that can document a more advanced level of development with the proposed CRF antagonist.

(3) NIDA will consider the amount and type of research and development resources the collaborator proposes to undertake as part of a proposed CRADA.

(4) NIDA will consider the background, experience, and expertise in medications development of the proposed collaborator.

Dated: February 1, 2000.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 00–2628 Filed 2–4–00; 8:45 am]

BILLING CODE 4140–01–M

[1] A review of the scientific literature on stress, drugs of abuse, and relapse to drug use is available upon request.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; 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 Center for Research Resources Special Emphasis Panel Comparative Medicine.

Date: February 10, 2000.

Time: 2:00 PM to 3 PM.

Agenda: To review and evaluate grant applications.

Place: Office of Review, National Center for Research Resources, 6705 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call)

Contact Person: Sybil A. Wellstood, PHD, Scientific Review Administrator, Office of Review, National Center for Research Resources, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892–7965, 301–435–0814.

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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: January 28, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00–2625 Filed 2–4–00; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of 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 a meeting of the National Advisory Council for Human Genome Research.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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/or contract proposals and the discussions could disclose confidential trade secrets or commrcial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Human Genome Research.

Date: February 28–29, 2000.

Open: February 28, 2000, 8:30 AM to 3:00 PM.

Agenda: Discussion of matters of program relevance.

Place: National Institutes of Health, Natcher Building, Conference Rooms E1 & E2, 45 Center Drive, Bethesda, MD 20892.

Closed: February 28, 2000, 3:00 PM to Adjournment on Tuesday, February 29, 2000.

Agenda: to review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Natcher Building, Conference Rooms E1&E2, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Elke Jordan, Deputy Director, National Human Genome Research Institute, National Institutes of Health, PHS,