

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.<sup>1</sup> 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 NIDA will sign appropriate confidential disclosure agreements in order to review proprietary and unpublished data.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.*

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## 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.*

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## 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 commercial 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,

<sup>1</sup> A review of the scientific literature on stress, drugs of abuse, and relapse to drug use is available upon request.